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Supreme Court, U.S.
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IN THE

Supreme Court of the United States

October Term, 1988

E. R. SQUIBB & SONS, INC.,

Petitioner,

-against-

MINDY HYMOWITZ and ROBERT ABRAMS,
ATTORNEY GENERAL OF THE STATE OF NEW YORK,

Respondents.

E. R. SQUIBB & SONS, INC.,

Petitioner,

-against-

ELIZABETH TIGUE, et al.,

Respondents.

E. R. SQUIBB & SONS, INC.,

Petitioner,

-against-

JANE DOLAN and ROBERT ABRAMS,
ATTORNEY GENERAL OF THE STATE OF NEW YORK,

Respondents.

APPENDIX TO PETITION FOR WRIT OF CERTIORARI TO THE COURT OF APPEALS OF THE STATE OF NEW YORK

ALLEN F. MAULSBY
CRAVATH, SWAINE & MOORE
One Chase Manhattan Plaza
New York, N.Y. 10005

BARRY M. EPSTEIN
MARC S. KLEIN
SILLS CUMMIS ZUCKERMAN RADIN
TISCHMAN EPSTEIN & GROSS
450 Park Avenue
New York, N.Y. 10022

DAVID A. BARRETT
Counsel of Record
DUKER & BARRETT
90 Broad Street
New York, N.Y. 10004
(212) 809-7700

ROBERT L. DICKSON
DAVID J. FLEMING
DICKSON, CARLSON & CAMPILLO
150 Broadway, Suite 1600
New York, N.Y. 10038

August 2, 1989

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APPENDIX A

Opinion of the New York Court of Appeals
(April 4, 1989)

STATE OF NEW YORK
COURT OF APPEALS

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1 No. 56
Mindy Hymowitz,
Respondent,
v.
Eli Lilly and Company, et al.,
Appellants,
and Merck & Co., Inc., et al.
Defendants,
Attorney General of the State of New York,
Intervenor-Respondent.

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1 No. 57
Elizabeth Tigue, et al.,
Respondents,
v.
E.R. Squibb & Sons, Inc., et al.
Appellants,
et al.,
Defendants.

OPINION

This opinion is uncorrected and subject to revision before publication in the New York Reports.

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1 No. 58
Jane Dolan, et al.,
Respondents,
v.
Eli Lilly & Company, et al.,
Appellants.
(and other actions.)
#151 actions

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1 No. 59
Barbara Hanfling, et al.
Respondents,
v.
Eli Lilly and Company, et al.
Appellants,
et al.,
Defendants.

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(56) Russel H. Beatie, Jr., Sanford N. Berland, Susan A. Winston, NYC, for appellant Lilly.
Robin J. Stout, Jay P. Mayesh, William A. Rome, NYC, for appellant Upjohn.

Robert M. Dato, David J. Fleming, Santa Monica, Barry M. Epstein, Lindsay H. Lew, NYC, for appellant Squibb.

Karl E. Seib, Jr., Robert D. Wilson, Jr., NYC, for appellant Abbott.

Paul D. Rheingold, NYC, for respondent Hymowitz.

Robert Abrams, Attorney General (Andrea Green, O. Peter Sherwood of counsel) for intervenor-respondent.

Herbert Semel, NYC, NY Public Interest Research Group, et al., *amici curiae*.

(57) Jay P. Mayesh, Burton N. Lipshie, Robin J. Stout, William A. Rome, NYC, for appellant Upjohn.

A. Edward Grashof, Thomas F. Clauss, Jr., Sheila M. Fessler, Paul A. Scrudato, NYC, for appellant Rexall.

Alexander C. Cordes, Paul K. Stecker, Buffalo; Marc S. Klein, Lindsay H. Lew, NYC; David J. Fleming, Robert M. Dato, Santa Monica, for appellant Squibb.

Charles M. McCaghey, William K. Dodds, NYC, for appellant Boyle.

John L. McGoldrick, Karl E. Seib, Jr., Theodore V.H. Mayer, John F. Brenner, NYC, for appellants Abbott et al.

Paul D. Rheingold, NYC, for respondents.

(58) Sharon E. Jaffe, Joseph A. DiBenedetto, Lisa A. Schoolman, NYC, for appellant Rorer.

Jay P. Mayesh, Burton N. Lipshie, Robin J. Stout, Carole W. Nimaroff, NYC, for appellant Upjohn.

Alexander C. Cordes, Paul K. Stecker, Buffalo; Marc S. Klein, Lindsay H. Lew, NYC, David J. Fleming, Robert M. Dato, Santa Monica, for appellant Squibb.

Russel H. Beatie, Jr., Sanford N. Berland, Susan A. Winston, NYC, for appellant Lilly.

William D. Fireman, NYC, for respondents Dolan et al.

Perry S. Reich, Sybil Shainwald, Steven M. Schapiro, NYC, for respondents Murphy.

(59) Karl E. Seib, Jr., Robert D. Wilson, Jr., NYC, for appellant Abbott.

Robin J. Stout, James T. Conlon, David M. Covey, Ann L. Wilson, NYC for appellant Upjohn.

W. Burlette Carter, Theodore V.H. Mayer, Charles Lozow, NYC, for appellant Merck.

Russel H. Beatie, Jr., Kenneth J. King, Charna L. Gerstenhaber, NYC, for respondent Lilly.

Arthur N. Luxenberg, Morris J. Eisen, Perry Weitz, NYC, for respondents.

WACHTLER, Ch. J.:

Plaintiffs in these appeals allege that they were injured by the drug diethylstilbestrol (DES) ingested by their mothers during pregnancy. They seek relief against defendant DES manufacturers. While not class actions, these cases are representative of nearly 500 similar actions pending in the courts in this state; the rules articulated by the Court here, therefore, must do justice and be administratively feasible in the context of this mass litigation. With this in mind, we now resolve the issue twice expressly left open by this Court, and adopt a market share theory, using a national market, for determining liability and apportioning damages in DES cases in which identification of the manufacturer of the drug that injured the plaintiff is impossible (*see, Kaufman v Lilly & Co.*, 65 NY2d 449, 456; *Bichler v Lilly & Co.*, 55 NY2d 571, 580). We also hold that the Legislature's revival for one year of actions for injuries

caused by DES that were previously barred by the statute of limitations (*see*, L 1986, ch 682, § 4) is constitutional under the State and Federal Constitutions.

I.

The history of the development of DES and its marketing in this country has been repeatedly chronicled (*see, e.g., Bichler v Lilly & Co., supra; Martin v Abbott Labs*, 102 Wash2d 581; *Sindell v Abbott Labs*, 26 Cal3d 588 *cert denied* 449 US 912; Sheiner, *DES and a Proposed Theory of Enterprise Liability*, 46 Ford L Rev 963). Briefly, DES is a synthetic substance that mimics the effect of estrogen, the naturally formed female hormone. It was invented in 1937 by British researchers, but never patented.

In 1941, the Food and Drug Administration (FDA) approved the New Drug Applications (NDA) of 12 manufacturers to market DES for the treatment of various maladies, not directly involving pregnancy. In 1947, the FDA began approving the NDAs of manufacturers to market DES for the purpose of preventing human miscarriages; by 1951, the FDA had concluded that DES was generally safe for pregnancy use, and stopped requiring the filing of NDAs when new manufacturers sought to produce the drug for this purpose. In 1971, however, the FDA banned the use of DES as a miscarriage preventative, when studies established the harmful latent effects of DES upon the offspring of mothers who took the drug. Specifically, tests indicated that DES caused vaginal adenocarcinoma, a form of cancer, and adenosis, a pre- cancerous vaginal or cervical growth.

Although strong evidence links prenatal DES exposure to later development of serious medical problems, plaintiffs seeking relief in court for their

injuries faced two formidable and fundamental barriers to recovery in this State; not only is identification of the manufacturer of the DES ingested in a particular case generally impossible, but, due to the latent nature of DES injuries, many claims were barred by the statute of limitations before the injury was discovered.

The identification problem has many causes. All DES was of identical chemical composition. Druggists usually filled prescriptions from whatever was on hand. Approximately 300 manufacturers produced the drug, with companies entering and leaving the market continuously during the 24 years that DES was sold for pregnancy use. The long latency period of a DES injury compounds the identification problem; memories fade, records are lost or destroyed, and witnesses die. Thus the pregnant women who took DES generally never knew who produced the drug they took, and there was no reason to attempt to discover this fact until many years after ingestion, at which time the information is not available.

We recognized this predicament in *Bichler v Lilly & Co.* (*supra* at 579), where the Court stated that in DES cases it is a "practical impossibility for most victims [to] pinpoint * * * the manufacturer directly responsible for their particular injury." We allowed plaintiff's recovery in that case, however, notwithstanding the failure of the plaintiff to identify the manufacturer of the injurious DES, on the limited basis that "the evidence was legally sufficient to support the jury verdict for the plaintiff" on the law as charged to the jury, and unobjected to by the defendant (*see, Kaufman v Lilly & Co.*, 65 NY2d 449, 456). The question, therefore, of whether non-identification of the manufacturer precludes plaintiffs from recovering for DES caused injuries, remained unresolved after *Bichler v Lilly & Co.* (*supra*).

The second barrier to recovery, involving the statutue of limitations, arose from the longstanding rule in this State that the limitations period accrued upon exposure in actions alleging personal injury caused by toxic substances (*Fleishman v Lilly & Co.*, 62 NY2d 888, *cert denied* 469 US 1192). In *Fleishman v Lilly & Co.* (*supra*) it became clear that this exposure rule led to many DES cases being barred by the statute of limitations before the discovery of injury; we held, however, that any change in the accrual date from exposure to discovery was more properly the prerogative of the Legislature (*id.* at 890; *see, id.* at 891 [Cooke, Ch. J., dissenting]). Four years after *Fleishman v Lilly & Co.* the Legislature addressed the statute of limitations problem, and instituted a discovery rule for "the latent effects of exposure to any substance" (L 1986, ch 682, §2). The Legislature also, for one year, revived causes of action for exposure to DES that had been time barred (L 1986, ch 682, § 4).

It is estimated that eventually 800 DES cases will be brought under the revival portion of this recent statute. Moreover, as indicated in *Bichler v Lilly & Co.* (*supra*), and as apparent from the record now before the Court, in the vast majority of these cases identification of the manufacturer of the DES that injured the plaintiff will be impossible. The Legislature, however, while reviving these time-barred actions, did not resolve the identification problem.

The present appeals are before the Court in the context of summary judgment motions. In all of the appeals defendants moved for summary judgment dismissing the complaints because plaintiffs could not identify the manufacturer of the drug that allegedly injured them. In three of the appeals defendants also moved on statute of limitations grounds, arguing that the revival of the

actions was unconstitutional under the State and Federal Constitutions, and that the complaints, therefore, are time barred and should be dismissed. The trial court denied all of these motions. On the statute of limitations issue, the trial court also granted plaintiffs' cross motions, [sic] dismissing defendants' affirmative defenses that the actions were time barred. The Appellate Division affirmed in all respects and certified to this Court the questions of whether the orders of the trial court were properly made. We answer these questions in the affirmative.

II.

In a products liability action, identification of the exact defendant whose product injured the plaintiff is, of course, generally required (*see, e.g., Morrissey v Conservative Gas Corp.*, 285 AD 825, *affd* 1 NY2d 741; Prosser & Keeton, Torts §103, at 713 [5th ed]). In DES cases in which such identification is possible, actions may proceed under established principles of products liability (*Bichler v Lilly Co. supra* at 579). The record now before us, however, presents the question of whether a DES plaintiff may recover against a DES manufacturer when identification of the producer of the specific drug that caused the injury is impossible.

A.

As we noted in *Bichler v Lilly Co.* (*supra* at 580, n5), the accepted tort doctrines of alternative liability and concerted action are available in some personal injury cases to permit recovery where the precise identification of a wrongdoer is impossible. However, we agree with the near unanimous vies of the high state courts that have considered the matter that these doctrines in their unaltered commonlaw forms do not permit recovery in DES cases (*see, e.g., Sindell v Abbott*

Labs, supra; Collins v Lilly & Co., 116 Wis2d 166; *Martin v Abbott Labs, supra; but see, Abel v Lilly & Co.*, 418 Mich 311 [held that there was a question of fact presented as to alternative liability and concerted action]).

The paradigm of alternative liability is found in the case of *Summers v Tice* (33 Cal2d 80). In *Summers* (*supra*), plaintiff and the two defendants were hunting, and defendants carried identical shotguns and ammunition. During the hunt, defendants shot simultaneously at the same bird, and plaintiff was struck by birdshot from one of the defendants' guns. The court held that where two defendants breach a duty to the plaintiff, but there is uncertainty regarding which one caused the injury, "the burden is upon such actor to prove that he has not caused the harm" (Restatement [Second] of Torts §433B[3]; *Bichler v Lily & Co., supra* at 580, n 5; *cf., Ravo v Rogatnick*, 70 NY2d 305 [successive tortfeasors may be held jointly and severally liable for an indivisible injury to the plaintiff]). The central rationale for shifting the burden of proof in such a situation is that without this device both defendants will be silent, and plaintiff will not recover; with alternative liability, however, defendants will be forced to speak, and reveal the culpable party, or else be held jointly and severally liable themselves. Consequently, use of the alternative liability doctrine generally requires that the defendants have better access to information than does the plaintiff, and that all possible tortfeasors be before the court (*see, Summers v Tice, supra* at 86; Restatement [Second] of Torts §433B, comment h). It is also recognized that alternative liability rests on the notion that where there is a small number of possible wrongdoers, all of whom breached a duty to the plaintiff, the likelihood that any of them injured the plaintiff is

relatively high, so that forcing them to exonerate themselves, or be held liable, is not unfair (*Sindell v Abbott Labs, supra* at 139).

In DES cases, however, there is a great number of possible wrongdoers, who entered and left the market at different times, and some of whom no longer exist. Additionally, in DES cases many years elapse between the ingestion of the drug and injury. Consequently, DES defendants are not in any better position than are plaintiffs to identify the manufacturer of the DES ingested in any given case, nor is there any real prospect of having all the possible producers before the court. Finally, while it may be fair to employ alternative liability in cases involving only a small number of potential wrongdoers, that fairness disappears with the decreasing probability that any one of the defendants actually caused the injury. This is particularly true when applied to DES where the chance that a particular producer caused the injury is often very remote (*Sindell v Abbot Labs, supra* at 603; *Collins v Lilly & Co., supra* at 184). Alternative liability, therefore, provides DES plaintiffs no relief.

Nor does the theory of concerted action, in its pure form, supply a basis for recovery. This doctrine, seen in dragTpart of all defendants having an understanding, express or tacit, to participate in "a common plan or design to commit a tortious act" (Prosser & Keeton, Torts §46, at 323 [5th ed]; *see Bichler v Lilly & Co., supra* at 580-581; *De Carvalho v Brunner*, 223 NY 284). As we noted in *Bichler v Lilly & Co.*, and as the present record reflects, drug companies were engaged in extensive parallel conduct in developing and marketing DES (*see, id.* at 585). There is nothing in the record, however, beyond this similar conduct to show any agreement, tacit or otherwise, to market DES for

pregnancy use without taking proper steps to ensure the drug's safety. Parallel activity, without more, is insufficient to establish the agreement element necessary to maintain a concerted action claim (*Sindell v Abbot Labs, supra* at 605; *Collins v Lilly & Co., supra* at 85; *Martin v Abbott Labs, supra* at 599.) Thus this theory also fails in supporting an action by DES plaintiffs.

In short, extant common law doctrines, unmodified, provide no relief for the DES plaintiff unable to identify the manufacturer of the drug that injured her. This is not a novel conclusion; in the last decade a number of courts in other jurisdictions also have concluded that present theories do not support a cause of action in DES cases. Some courts, upon reaching this conclusion, have declined to find any judicial remedy for the DES plaintiffs who cannot identify the particular manufacturer of the DES ingested by their mothers (*see, Zafft v Lilly & Co.*, 67 SW2d 241 [Mo] [en banc]; *Mulcahy v Lilly & Co.*, 386 NW2d 67 [Iowa] [stating that any change in the law to allow for recovery in non-identification DES cases should come from the legislature]). Other courts, however, have found that some modification of existing doctrine is appropriate to allow for relief for those injured by DES of unknown manufacture (*e.g., Sindell v Abbot [sic] Labs, supra; Collins v Lilly & Co., supra; Martin v Abbott Labs, supra*).

We conclude that the present circumstances call for recognition of a realistic avenue of relief for plaintiffs injured by DES. These appeals present many of the same considerations that have prompted this Court in the past to modify the rules of personal injury liability, in order "to achieve the ends of justice in a more modern context" (*see, People v Hobson*, 39 NY2d 479, 489; Codling V Paglia, 32 NY2d 330, 341), and we perceive that here

judicial action is again required "to overcome the inordinately difficult problems of proof" caused by contemporary products and marketing techniques (*see, Bichler v Lilly & Co., supra* at 579-580 [*quoting Caprara v Chrysler Corp.*, 52 NY2d 114, 123]).

Indeed, it would be inconsistent with the reasonable expectations of a modern society to say to these plaintiffs that because of the insidious nature of an injury that long remains dormant, and because so many manufacturers, each behind a curtain, contributed to the devastation, the cost of injury should be borne by the innocent and not the wrongdoers. This is particularly so where the legislature consciously created these expectations by reviving hundreds of DES cases. Consequently, the ever-evolving dictates of justice and fairness, which are the heart of our common-law system, require formation of a remedy for injuries caused by DES (*see, Woods v Lancet*, 303 NY 349, 355; see, also, Kaye, *The Human Dimension in Appellate Judging: A Brief Reflection on a Timeless Concern*, 73 Cornell L. Rev. 1004).

We stress, however, that the DES situation is a singular case, with manufacturers acting in a parallel manner to produce an identical, generically marketed product, which causes injury many years later, and which has evoked a legislative response reviving previously barred actions. Given this unusual scenario, it is more appropriate that the loss be borne by those that produced the drug for use during pregnancy, rather than by those who were injured by the use, even where the precise manufacturer of the drug cannot be identified in a particular action. We turn then to the question of how to fairly and equitably apportion the loss occasioned by DES, in a case where the exact manufacturer of the drug that caused the injury is unknown.

B.

The past decade of DES litigation has produced a number of alternative approaches to resolve this question. Thus, in a sense, we are now in an enviable position; the efforts of other courts provided examples for contending with this difficult issue, and enough time has passed so that the actual administration and real effects of these solutions now can be observed. With these useful guides in hand, a path may be struck for our own conclusion.

First, this Court's opinion in *Bichler v Lilly & Co.* (*supra*) must be considered. There the jury was instructed on a modified version of concerted action, which, in effect, substituted the fact of conscious parallel activity by manufacturers for the usual common law requirement that there be proof of an actual agreement between actors to jointly act tortiously (*id.* at 584). The defendant in Bichler did not object to this instruction, and the modified concerted action theory became the law applicable to that particular case (*id.* at 583- 584).

Now given the opportunity to assess the merits of this theory, we decline to adopt it as the law of this State. Parallel behavior, the major justification for visiting liability caused by the product of one manufacturer upon the head of another under this analysis, is a common occurrence in industry generally. We believe, therefore, that inferring agreement from the fact of parallel activity alone improperly expands the concept of concerted action beyond a rational or fair limit; among other things, it potentially renders small manufacturers, in the case of DES and in countless other industries, jointly liable for all damages stemming from the defective products of an entire industry (accord, *Sindell v Abbot Labs, supra* at 605).

A narrower basis for liability, tailored more closely to the varying culpableness of individual DES producers, is the market share concept. First judicially articulated by the California Supreme Court in *Sindell v Abbott Labs (supra)*, variations upon this theme have been adopted by other courts (*see, Collins v Lilly & Co., supra; Martin v Abbott Labs, supra*). In *Sindell v Abbott Labs* (*supra*), the Court synthesized the market share concept by modifying the *Summers v Tice* (*supra*) alternative liability rationale in two ways. It first loosened the requirement that all possible wrongdoers be before the court, and instead made a "substantial share" sufficient. The court then held that each defendant who could not prove that it did not actually injure plaintiff would be liable according to that manufacturer's market share. The court's central justification for adopting this approach was its belief that limiting a defendant's liability to its market share will result, over the run of cases, in liability on the part of a defendant roughly equal to the injuries the defendant actually caused (*id.* at 612).

In the recent case of *Brown v Superior Court* (44 Cal3d 1049), the California Supreme Court resolved some apparent ambiguity in *Sindell v Abbott Labs*, and held that a manufacturer's liability is several only, and, in cases in which all manufacturers in the market are not joined for any reason, liability will still be limited to market share, resulting in a less than 100% recovery for a plaintiff. Finally, it is noteworthy that determining market shares under *Sindell v Abbott Labs* proved difficult and engendered years of litigation. After attempts at using smaller geographical units, it was eventually determined that the national market provided the most feasible and fair solution, and this national market information was compiled (*see, In re Complex DES Litigation*, No. 830/109 Cal Super Ct).

Four years after *Sindell v Abbott Labs*, the Wisconsin Supreme Court followed with *Collins v Lilly & Co.* (116 Wis2d 166). Deciding the identification issue without the benefit of the extensive California litigation over market shares, the Wisconsin court held that it was prevented from following *Sindell* due to "the practical difficulty of defining and proving market share" (*id.* at 189). Instead of focusing on tying liability closely to the odds of actual causation, as the *Sindell* court attempted, the *Collins* court took a broader perspective, and held that each defendant is liable in proportion to the amount of risk it created that the plaintiff would be injured by DES. Under the *Collins* structure, the "risk" each defendant is liable for is a question of fact in each case, with market shares being relevant to this determination (*id.* at 191, 200). Defendants are allowed, however, to exculpate themselves by showing that their product could not have caused the injury to the particular plaintiff (*id.* at 198).

The Washington Supreme Court, writing soon after *Collins v Lilly & Co.*, took yet another approach (*see, Martin v Abbott Labs*, 102 Wash2d 581). The Martin court first rejected the *Sindell* market share theory due to the belief (which later proved to be erroneous in *Brown v Superior Court* [*supra*]) that California's approach distorted liability by inflating market shares to ensure plaintiffs of full recovery (*id.* at 601). The *Martin* court instead adopted what it termed "market share alternative liability," justified, it concluded, because "[e]ach defendant contributed to the risk of injury to the public, and consequently, the risk to individual plaintiffs" (*id.* at 604).

Under the Washington scheme, defendants are first allowed to exculpate themselves by proving by the preponderance of the evidence that they were not the

manufacturer of the DES that injured plaintiff. Unexculpated defendants are presumed to have equal market shares, totalling 100%. Each defendant then has the opportunity to rebut this presumption by showing that its actual market share was less than presumed. If any defendants succeed in rebutting this presumption, the liability shares of the remaining defendants who could not prove their actual market share are inflated, so that the plaintiff received a 100% recovery (*id.* at 605-606).[1] The market shares of defendants is a question of fact in each case, and the relevant market can be a particular pharmacy, or county, or state, or even the country, depending upon the circumstances the case presents (*George v Parke-Davis, supra*).

Turning to the structure to be adopted in New York, we heed both the lessons learned through experience in other jurisdictions and the realities of the mass litigation of DES claims in this State. Balancing these considerations, we are led to the conclusion that a market share theory, based upon a national market, provides the best solution. As California discovered, the reliable

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[1]The actual operation of this theory proved more mathematically complex when the court was presented with the question of what to do about unavailable defendants. Recognizing that the possibility of abuse existed when defendants implead unavailable defendants, who would then be assumed to have had an equal share of the market, the court placed the burden upon appearing defendants to prove the market share of the absent ones (*George v Parke-Davis*, 107 Wash2d 584). If this can be proved, the plaintiff simply cannot recover the amount attributable to the absent defendant, and thus recovery in the case is less than 100%. If the market share of the absent defendant cannot be shown, the remaining defendants who cannot proved their market shares have their shares inflated to provide plaintiff with full recovery. Finally, if all appearing defendants can prove their market shares, their shares are never inflated, regardless of whether the market share of a non-appearing defendant can be proved or not; thus, in this situation, the plaintiff again will not recover her full damages (*id.*).

determination of any market smaller than the national one likely is not practicable. Moreover, even if it were possible, of the hundreds of cases in the New York courts, without a doubt there are many in which the DES that allegedly caused injury was ingested in another State. Among the thorny issues this could present, perhaps the most daunting is the specter that the particular case could require the establishment of a separate market share matrix. We feel that this is an unfair, and perhaps impossible burden to routinely place upon the litigants in individual cases.

Nor do we believe that the Wisconsin approach of assessing the "risk" each defendant caused a particular plaintiff, to be litigated anew as a question of fact in each case, is the best solution for this State. Applied on a limited scale this theory may be feasible, and certainly is the most refined approach by allowing a more thorough consideration of how each defendant's actions threatened the plaintiff. We are wary, however, of setting loose, for application in the hundreds of cases pending in this State, a theory which requires the factfinder's individualized and open-ended assessment of the relative liabilities of scores of defendants in every case. Instead, it is our perception that the injustices arising from delayed recoveries and inconsistent results which this theory may produce in this State outweigh arguments calling for its adoption.

Consequently, for essentially practical reasons, we adopt a market share theory using a national market. We are aware that that [sic] the adoption of a national market will likely result in a disproportion between the liability of individual manufacturers and the actual injuries each manufacturer caused in this State. Thus our market share theory cannot be founded upon the belief that, over the run of cases, liability will

approximate causation in this State (*see, Sindell v Abbott Labs, supra* at 612). Nor does the use of a national market provide a reasonable link between liability and the risk created by a defendant to a particular plaintiff (see, Collins v Lilly & Co. *supra*; Martin v Abbot Labs, *supra*). Instead, we choose to apportion liability so as to correspond to the overall culpability of each defendant, measured by the amount of risk of injury each defendant created to the public at large. Use of a national market is a fair method, we believe, of apportioning defendants' liabilities according to their total culpability in marketing DES for use during pregnancy. Under the circumstances, this is an equitable way to provide plaintiffs with the relief they deserve, while also rationally distributing the responsibility for plaintiffs' injuries among defendants.

To be sure, a defendant cannot participate in the marketing of DES for pregnancy use; if a DES producer satisfies its burden of proof of showing that it was not a member of the market of DES sold for pregnancy use, disallowing exculpation would be unfair and unjust. Nevertheless, because liability here is based on the overall risk produced, and not causation in a single case, there should be no exculpation of a defendant who, although a member of the market producing DES for pregnancy use, appears not to have caused a particular plaintiff's injury. It is merely a windfall for a producer to escape liability solely because it manufactured a more identifiable pill, or sold only to certain drugstores. These fortuities in no way diminish the culpability of a defendant for marketing the product, which is the basis of liability here.[2]

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[2]Various defendants argue here that although they produced DES, it was not sold for pregnancy use. If a defendant was not a member of the national market of DES marketed for pregnancy, it is not

Finally, we hold that the liability of DES producers is several only, and should not be inflated when all participants in the market are not before the court in a particular case. We understand that, as a practical matter, this will prevent some plaintiffs from recovering 100% of their damages. However, we eschewed exculpation to prevent the fortuitous avoidance of liability, and thus, equitably, we decline to unleash the same forces to increase a defendant's liability beyond its fair share of responsibility.[3]

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culpable, and should not be liable. Consequently, if a particular defendant sold DES in a form unsuitable for use during pregnancy, or if a defendant establishes that its product was not marketed for pregnancy use, there should be no liability. From the record before the Court here, however, the facts are not developed well enough to establish that any defendants were not in the national market of DES sold for pregnancy use. Thus summary judgment cannot at this time be granted on this issue as to any defendants.

[3]The dissenter misapprehends the basis for liability here. We have not by the backdoor adopted a theory of concerted action. We avoided extending this theory, because its concomitant requirement of joint and several liability expands the burden on small manufactuers beyond a rational or fair limit. This result is reached by the dissent, not by the majority, so that criticism on this front is misplaced.

We are confronted here with an unprecedented identification problem, and have provided a solution that rationally apportions liability. We have heeded the practical lessons learned by other jurisdictions, resulting in our adoption of a national market theory with full knowledge that it concedes the lack of a logical link between liability and causation in a single case. The dissent ignores these lessons, and, endeavoring to articulate a theory it perceives to be closer to traditional law, sets out a construct in which liability is based upon chance, not upon the fair assessment of the acts of defendants. Under the dissent's theory, a manufacturer with a large market share may avoid liability in many cases just because it manufactured a memorably shaped pill. Conversely, a small manufacturer can be held jointly liable for the full amount of every DES injury in this State simply because the shape of its product

III.

The constitutionality of the revival statute remains to be considered (*see*, L 1986, ch 682, §4). This section revives, for the period of one year, actions for damages caused by the latent effects of DES, tungsten carbide, asbestos, chlordane, and polyvinylchloride. Defendants argue that the revival of barred DES claims was unconstitutional as a denial of both due process and equal protection, under the State and Federal Constitutions (*see* NY Const art 1, §§6, 11; US Const, 14th Amend, §1). We are concerned here only with the constitutionality of the statute as it pertains to DES; there are no producers of the other substances, or plaintiffs alleging injury therefrom, before the Court on these appeals.

The federal due process clause provides very little barrier to a state legislature's revival of time-barred actions (*see, Chase Securities Corp v Donaldson*, 325 US 304). In Chase, the United States Supreme Court upheld the revival of a time barred action, stating that statutes of limitation "represent a public policy about the privilege to litigate * * * the history of pleas shows them to be good only by legislative grace and to be subject to a relatively large degree of legislative control" (*id.* at 314). Under state law, the level of review seems

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was not remarkable, even though the odds, realistically, are exceedingly long that the small manufacturer caused the injury in any one particular case.

Therefore, although the dissent's theory based upon a "shifting the burden of proof" and joint and several liability is facially reminiscent of prior law, in the case of DES it is nothing more than advocating that bare fortuity be the test for liability. When faced with the novel identification problem posed by DES cases, it is preferable to adopt a new theory that apportions fault rationally, rather than to contort extant doctrines beyond the point at which they provide a sound premise for determining liability.

somewhat more stringent. In *Gallewski v Hentz* (301 NY 164, 174) the Court stated that "the Legislature may constitutionally revive a personal cause of action where the circumstances are exceptional and are such as to satisfy the Court that serious injustice would result to plaintiffs not guilty of any fault if the intentions of the Legislature were not effected." It appears, however, that we have applied a less strict test in other cases, and have been satisfied if there was an apparent injustice which "calls for a remedy," and which is "reasonable" and not "arbitrary." (*Robinson v Robbins Dry Dock & Repair Co.*, 238 NY 271, 279-280).

We need not light upon a precise test here, however, because the Legislature's revival of DES claims meets the highest standard. For at least 25 years this Court maintained an exposure rule for toxic substances, because it was felt that change in this area was the responsibility of the Legislature (*see, e.g., Schwartz v Heyden Newport*, 12 NY2d 212, 220; *Fleishman v Lilly & Co., supra* at 890). Indeed, in *Fleishman v Lilly & Co.* (*supra*) the Legislature's attention was drawn specifically to DES by the majority, which stated that any change in the exposure rule was the Legislature's role.

The Legislature has now revived DES actions that were time barred under the exposure rule, while also instituting a discovery rule for future application (L 1986, ch 682, §4; CPLR 214-c). The latent nature of DES injuries is well known, and it is clear that in the past the exposure rule prevented the bringing of timely actions for recovery. Thus we believe that exceptional circumstances are presented, that an injustice has been rectified, and that the requirements of *Gallewski v Hentz* (*supra*) have been met.

Defendants argue further that, even if the statute is generally valid, it may be unconstitutionally applied in cases in which the plaintiff could have sued originally, but did not. It does seem that some plaintiffs may have known of their injuries a day, or a week, a month, or perhaps longer, before the original limitations period ran. Some may have known of their exposure, but did not develop injuries during the limitations period. Others may have known of some effect upon them of DES exposure, which became cancerous only after any action would have been time barred. Under these circumstances, the Legislature properly determined that it would be more fair for all plaintiffs to uniformly now have one year to bring their actions, rather than for the courts to begin drawing arbitrary lines transecting this area's shades of gray.

Defendants also argue that the revival statute violates equal protection, because the Legislature designated only five substances for revival, including DES, while instituting a prospective only discovery rule for other substances. Defendants claim that this categorization is without sufficient basis, and that it is the result of a "political compromise." But most, if not all legislation is the product of some compromise, so that this objection surely is no basis for finding the revival statute unconstitutional. Instead, here we must proceed on the presumption that the law is constitutional, and will hold otherwise only if it is established that the distinction drawn has no reasonable basis (*Trump v Chu*, 62 NY2d 20; *Montgomery v Daniels*, 38 NY2d 41, 61). Moreover, because defendants allege no impairment of a fundamental right, the Legislature has substantial leeway in making classifications in this area of "economics and social welfare" (*see, Montgomery v Daniels, supra*, [*quoting Dandridge v Williams*, 397 US 471, 485]).

As it pertains to DES, surely the revival statute has a rational basis, and the Legislature acted within its broad range of discretion in enacting the law. The number of DES-caused injuries was relatively well known by the Legislature, which allowed for the ramifications of revival of DES claims, such as the effect on insurance interests, and the other costs, to be reasonably predicted (Record of Proceedings, New York Assembly [June 24, 1986][statement of Assemblyman M. H. Miller]). Furthermore, it was also well known, particularly after *Fleishman v Lilly* (*supra*), that DES victims were prejudiced under current law. This, we believe, is enough of a basis for the Legislature to revive DES claims now, and wait as to other substances until it is felt that these substances present a problem suitable for resolution. The Legislature does not violate equal protection by providing a rational piecemeal remedy for what may be a larger problem (*Williamson v Lee Optical*, 348 US 483).

Accordingly, in each case the order of the Appellate Division should be affirmed, with costs, and the certified question answered in the affirmative.

Hymowitz v Eli Lilly - Case No. 56
Tigue v E.R. Squibb - Case No. 57
Dolan v Eli Lilly - Case No. 58
Hanfling v Eli Lilly - Case No. 59

MOLLEN, J. (concurring in *Hymowitz* and *Hanfling*; and dissenting in part in *Tigue* and *Dolan*):

The issue presented to the Court in this appeal is to determine whether the revival statute for DES claims is constitutional and has properly "opened the window" to enable injured parties to recover for their injuries caused by DES and, if so, how to best enable such plaintiffs to overcome the practical impossibility of

bearing their normal burden of proof of demonstrating that the defendants caused their injuries. The majority has selected one approach to meet this issue. However, I am compelled to concur in part and dissent in part because I am convinced that another more appropriate method of approaching this issue is fairer and more just and equitable to the plaitniffs and to those defendants who could not have caused the plaintiff's injuries, and which is consistent with established principles of tort law. I concur with the majority's conclusion that the revival statute is, in all respects, constitutional and may be relied upon by the plaintiffs herein. I am also in complete agreement with the majority's view that the market share theory of liability, based upon a national market, is an appropriate means by which to accord DES plaintiffs an opportunity to seek recovery for their injuries. However, I respectfully disagree with the majority's conclusion that there should be no exculpation of those defendants who produced and marketed DES for pregnancy purposes, but who produced and marketed DES for pregnancy purposes, but who can prove, by a preponderance of the evidence, that they did not produce or market the particular pill ingested by the plaintiff's mother. Moreover, in order to ensure that these plaintiffs receive full recovery of their damages, as they are properly entitled to by any fair standard, I would retain the principle of imposing joint and several liability upon those defendants which cannot exculpate themselves.

The emergence of the market share concept of liability in the field of products liability reflects a recognition by several jurisdictions throughout the United States that due to the incidence of mass production and marketing of various drugs and fungible goods, consumers are many times harmed by a product which

is not easily traceable to a specific manufacturer, particularly in those situations where the harm occurred many years prior to the discovery of the injuries and the cause thereof. Such is the situation in the DES cases now before us. Under traditional common law tort principles, a plaintiff is required to establish the existence of a causal relationship between the act or omission of the defendant or defendants and the injury sustained (*see, Morrissey v Conservative Gas Corp.*, 1 NY2d 741; Prosser & Keeton, Torts § 41, at 262). However, given the reality of the situation in DES cases, including the lengthy passage of time, the generic form of most DES pills and the unavailability of pharmaceutical and physician records, it is, as a practical matter, impossible for most DES plaintiffs to bear the burden of proof of establishing the traditional tort element of causation.

Moreover, as noted by the majority, the tort doctrines of alternative liability and concerted action, both of which provide for recovery in situations where a plaintiff, through no fault of his or her own, cannot identify the actual wrongdoer, do not provide appropriate relief to these DES plaintiffs. Unlike the scenario present in the DES cases, the principle of alternative liability presupposes that the number of possible wrongdoers are few in number, that one of the joined defendants had to have actually caused the plaintiff's injury and that the defendants are in a much better position than the plaintiff to identify the actual wrongdoer and, therefore, the burden is shifted to the defendants to prove who was the actual wrongdoer and who among them are to be exculpated (*see, Summers v Tice*, 33 Cal2d 80; Restatement [Second] of Torts 433B[3]). However, in view of the difference in the factual circumstances, the theory of alternative liability does not provide a workable solution for DES plaintiffs.

The concept of concerted action liability requires, *inter alia*, that the plaintiff prove that all of the joined defendants had an understanding, expressed or implied, to participate in a common plan or design to commit a tortious act or to lend assistance to the wrongdoer (*see*, Prosser & Keeton, Torts § 46, at 323). Typically, DES plaintiffs allege that the concerted action of the DES manufacturers consisted of using one another's marketing techniques, relying upon each other's testing and encouraging one another to market DES without performing adequate testing or warnings. The courts, with few exceptions (*see, e.g., Abel v Lilly & Co.*, 418 Mich. 311), have rejected the applicability of concerted action liability to DES cases because the plaintiffs cannot establish the existence of an express or tacit agreement among DES manufacturers to market or produce DES without proper testing or warnings (*see, e.g., Sindell v Abbott Labs*, 26 Cal3d 588, *cert denied* 499 US 912; *Martin v Abbott Labs*, 102 Wash2d 581; *Collins v Lilly & Co.*, 116 Wis2d 166). The parallel or imitative conduct of DES manufacturers in producing and/or marketing DES, as the majority expressly notes, is insufficient, in and of itself, to establish concerted action liability (slip opinion, p 12).

The principle of market share litigation was first espoused by the California Supreme Court in *Sindell v Abbott Labs* (*supra*), as a valid theory of manufacturer's liability based upon each manufacturer's share of the market. This approach provides DES plaintiffs with a means by which to recover damages for their injuries without the plaintiffs being held to the traditional tort requirement of identifying the actual wrongdoer. The public policy underpinnings of the *Sindell* rationale is that, from a perspective of fairness and equity, the DES manufacturers are in a better position than the

innocent plaintiffs who have sustained grievous injuries to bear the cost of such injuries. Thus, the *Sindell* court held that once a plaintiff has joined a "substantial share" of the DES manufacturers of the relevant market in the action and has established that the sustained injuries were caused by the ingestion of DES by the plaintiff's mother during pregnancy, the burden of proof shifts to each defendant to demonstrate, by a preponderance of the evidence, that it did not produce or market the pill ingested by the plaintiff's mother. Those DES defendants who could not exculpate themselves, would then be liable for the proportion of the judgment which represented its share of the market. The intended result of the *Sindell* approach is that, "each manufacturer's liability for an [particularly DES] injury would be approximately equivalent to the damage caused by the DES it manufactured" (*supra*, p 613).

The Wisconsin and Washington Supreme Courts subsequently adopted collective liability theories in DES cases based upon similar policy considerations; namely, as between the injured plaintiffs and the negligent defendants, the latter should bear the cost of injury (*Collins v Lilly Co.*[sic], 116 Wis2d 166, *supra*; *Martin v Abbott Labs*, 102 Wash2d 581, *supra*). Both the Collins and Martin courts reasoned that since all of the DES manufacturers and distributors contributed to the risk of injury to the public and, consequently, the risk of injury to individual plaintiffs, each defendant shared, in some measure, a degree of culpability in producing or marketing DES. In *Collins*, the Wisconsin Supreme adopted a "risk contribution" theory of liability, and, in *Martin*, the Washington Supreme Court adopted what it termed a "market share alternative liability" theory. These two approaches differ from the *Sindell* theory primarily in the manner in which the damages are

apportioned. Significantly, both the Supreme Courts of Wisconsin and Washington in the *Collins* and *Martin* cases, as did the Supreme Court of California in *Sindell*, provided that the joined or impleaded defendants may exculpate themselves from liability if they can establish, by a preponderance of the evidence, that they did not produce or market the particular DES pill taken by the plaintiff's mother. Notably, in *Collins*, the Wisconsin Supreme Court explained that it would not adopt a risk contribution theory which would have imposed liability solely upon the DES defendants' participation in the creation of the risk of injury even though some of the defendants could establish that they could not have actually caused the plaintiff's injury. The *Collin's* court noted, "(w)e still require it be shown that the defendant drug company reasonably could have contributed in some way to the actual injury" (*supra*, p 191, n 10). In fact, none of the jurisdictions which have adopted varying theories of collective liability in DES cases, has refused to permit exculpation of those defendants which have been able to prove that they could not have produced or marketed the pill which caused the particular plaintiff's injuries, thereby recognizing that to preclude exculpation would directly and unnecessarily contravene the established common law tort principles of causation (*see, Sindell v Abbott Labs, supra; Collins v Lilly & Co., supra; Martin v Abbott Labs, supra; Abel v Eli Lilly Co., supra; McCormack v Eli Lilly & Co., supra; see also, Burnside v Abbott Labs*, 351 Pa S 264).

Clearly, the development and underlying purpose of the various concepts of liability in DES cases has been to provide a means whereby the plaintiffs, who cannot identify the actual manufacturer of the pill ingested by their mother, are alleviated of the traditional burden

of proof of causation and to shift that burden to the defendants. The various theories of collective liability which have been adopted in the several jurisdictions in an effort to provide plaintiffs with a means to recovery for their injuries, were not intended to, and did not, provide DES plaintiffs with an unprecedented strict liability cause of action. However, the majority herein, by precluding exculpation of those defendants in DES cases who produced DES for pregnancy purposes but who can establish, by a preponderance of the evidence, that they did not and could not have produced or marketed the pill which caused the plaintiff's injuries, has created such a radical concept and purports to limit it to DES claims. In the majority's view, the defendant's liability in DES cases is premised upon the overall risk of injury which they created to the public at large in producing and marketing DES for pregnancy purpose and, therefore, exculpation of those defendants who can establish that the plaintiff's mother did not ingest their pill, would be inconsistent with the overall risk theory of liability. By taking this view, however, the majority, while stating that it is adopting a market share theory of liability, is, in essence, despite its disclaimer of doing so, adopting a concerted action theory of liability, but has eliminated therefrom the requirement that the plaintiffs establish that the defendants tacitly agreed to produce and market DES for pregnancy use without proper testing and without adequate warnings of the potential dangers involved. Such a result, represents a radical departure from fundamental tenets of tort law and is unnecessarily unfair and inequitable to the defendants who have proven, or can prove, that they did not produce the pill which caused the injury. Moreover, this result is directly contrary to the majority's own statement that it is rejecting the "conscious

parallelism" theory utilized in *Bichler v Eli Lilly & Co.* (79 AD2d 317, *affd* 55 NY2d 571), because, as stated by the majority herein, "(p)arallel behavior, the major justification for visiting liability by the product of one manufacturer upon the head of another under this analysis, is a common occurrence in industry generally. We believe, therefore, that inferring agreement from the act of parallel activity alone improperly expands the concept of concerted action beyond a rational or fair limit; among other things, it potentially renders small manufacturers in the case of DES and in countless other industries, jointly liable for all the damages stemming from the defective products of an entire industry" (slip opinion, p 12).

I fully concur with the above stated position of the majority and thus, I cannot agree that the imposition of liability on drug companies, in this case DES manufacturers, solely upon their contribution, in some measure, to the risk of injury by producing and marketing a defective drug, without any consideration given to whether the defendant drug companies actually caused the plaintiff's injuries, is appropriate or warranted. Rather, I would adopt a market share theory of liability, based upon a national market, which would provide for the shifting of the burden of proof on the issue of causation to the defendants and would impose liability upon all of the defendants who produced and marketed DES for pregnancy purposes, except those who were able to prove that their product could not have caused the injury. Under this approach, DES plaintiffs, who are unable to identify the actual manufacturer of the pill ingested by their mother, would only be required to establish, (1) that the plaintiff's mother ingested DES during pregnancy; (2) that the plaintiff's injuries were caused by DES; and (3) that

the defendant or defendants produced and marketed DES for pregnancy purposes. Thereafter, the burden of proof would shift to the defendants to exculpate themselves by establishing, by a preponderance of the evidence, that the plaintiff's mother could not have ingested their particular pill. Of those defendants who are unable to exculpate themselves from liability, their respective share of the plaintiff's damages would be measured by their share of the national market of DES produced and marketed for pregnancy purposes during the period in question.

I would further note that while, on the one hand, the majority would not permit defendants who produced DES for pregnancy purposes to exculpate themselves, the majority at the same time deprives the plaintiffs of the opportunity to recover fully for their injuries by limiting the defendants' liability for the plaintiff's damages to several liability. In my view, the liability for the plaintiff's damages of those defendants who are unable to exculpate themselves should be joint and several thereby ensuring that the plaintiffs will receive full recovery of their damages. In addition to being fair to the DES plaintiffs, the imposition of joint and several liability is consistent with that portion of the revival statute which specifically exempted DES claims from those provisions which provide, with certain exceptions, for several liability of joint tortfeasors (*see*, L. 1986, ch. 682, § 12; CPLR 1600 *et seq.*). Moreover, in order to ease the financial burden on the specific defendants named in the lawsuit, the defendants would have the option of seeking contribution from their fellow defendants for damages in excess of each defendant's particular market share, and a defendant should be permitted leave to implead those DES manufacturers who the plaintiff has not joined, in order to ensure,

where possible, full contribution (*see, e.g., Dole v Dow Chemical Co.*, 30 NY2d 143). Admittedly, adherence to joint and several liability could result in disproportion between a defendant's potential liability for the damages suffered by the plaintiff and defendant's actual national market share; however, the opportunity to present exculpatory evidence reduces the risk of imposing liability on innocent defendants.

The application of the aforesaid principles, although somewhat innovative and a modification of traditional tort law, (i.e., the burden of proof is on the plaintiff to prove proximate causation) would, in view of the exigent circumstances, be in furtherance of a valid public policy of imposing the burden of bearing the cost of severe injuries upon those who are responsible for placing into the stream of commerce the causative instrumentality of such injuries. Adherence to this principle would not be too dissimilar from the accepted doctrine of *res ipsa loquitor* which provides, in essence, that where an instrumentality which caused the plaintiff's injuries was in the exclusive control of the defendant and the accident which occurred is one which would not ordinarily happen without negligence, these facts are sufficient to justify an inference of negligence and to shift the burden upon the defendant of coming forward with an explanation (*see, e.g., Galbraith v Busch*, 267 NY 230, 234; Richardson, Evidence § 93, p 68 [Prince 10th ed]). Thus, this approach, unlike that taken by the majority, does not represent an unnecessary and radical departure from basic principles of tort law. By characterizing this approach as "nothing more than advocating that bare fortuity be the test for liability" (slip opinion p 19, n 3) the majority fails to perceive that this is no more and no less than a basic principle of tort law; i.e., a plaintiff may not recover for his injuries from a defendant who

could not have caused those injuries. When the majority eliminates this fundamental causative factor as a basis for recovery, it effectively indulges in the act of judicial legislating. I would further note that if the Legislature had intended to adopt this radical approach which is at total variance with traditional tort law, it could readily have done so when it enacted the revival statute for, among others, DES plaintiffs. Its refusal to do so can certainly not be deemed to be an invitation to this Court to assume the legislative role.

Judged by the aforesaid standard, I conclude that the trial courts' orders in *Tigue & Margolies v E.R. Squibb* (Case No. 57) and *Dolan v Eli Lilly* (Case No. 58), to the extent that they denied the summary judgment motions of the defendant The Upjohn Company ("Upjohn") in both actions and the defendant Rexall Drug Company ("Rexall") in the *Tigue* action, were improper. In *Tigue*, Mrs. Tigue, the plaintiff's mother, testified that the DES pill she ingested while she was pregnant with the plaintiff was a white, round tablet (R 709-710). Similarly, Myrna Margolies' mother testified that the DES pill she ingested was a dark red, hard, round pill (R 224-226). Mr. Margolies, the plaintiff's father, also recalled that the pills were a reddish color and Mrs. Margolies' obstetrician stated that the DES pill he prescribed to his patients was not an Upjohn product. Moreover, in the *Dolan,* action, Mrs. Dolan, the plaintiff's mother, stated that the DES pill she took was a white, round, hard tablet (R 321; 303). This fact was corroborated by Mr. Dolan's testimony (R 414; 444). Finally, it was established that Upjohn's DES pill which was produced and marketed for pregnancy purposes, was in the form of a "perle" which is a pharmaceutical term for a dose form consisting of a soft elastic capsule

containing a liquid center (R 2182). Based on the evidence submitted in support of Upjohn's summary judgment motions in these two cases, I would conclude that the plaintiffs have failed to adduce sufficient proof in admissible form to raise a triable issue of fact as to whether their mothers ingested an Upjohn DES pill. Accordingly, Upjohn's motion for summary judgment in those actions should have been granted.

Additionally, in *Tigue & Margolies v E.R. Squibb* (Case No. 57), Rexall's motion for summary judgment should have been granted since the plaintiffs failed to raise a triable issue of fact as to whether their mothers could have ingested a Rexall DES product during the pregnancies in question. The evidence submitted in support of Rexall's motion established that until 1978, Rexall sold its products, including its DES pill, *exclusively* to Rexall Drug Stores (R 1934, 22003-04; 2210). The testimony of the plaintiffs' parents, Mrs. Tigue and Mr. and Mrs. Margolies established that they had purchased their DES prescriptions from non-Rexall pharmacies during the periods of their respective pregnancies, i.e., 1960 and 1953. Based on this uncontroverted evidence demonstrating Rexall's non-involvement in these plaitniffs' injuries, Rexall's motion for summary judgment should have been granted.

As to those defendants which seek to exculpate themselves from liability in these various actions based upon the fact that they produced and marketed DES solely for non-pregnancy purposes, we agree with the majority's conclusion that the record before the Court is factually insufficient to establish that they were not in the national market of DES sold for pregnancy use (see, slip opinion, p 18, n 2). Accordingly, their summary judgment motions were properly denied.

* * * * * * * * * * * * * * * * * * * *

In Case Nos. 56 and 59: Order affirmed, with costs, and certified question answered in the affirmative. Opinion by Chief Judge Wachtler. Judges Alexander, Titone and Hancock concur. Judge Mollen concurs in a separate opinion. Judges Simons, Kaye and Bellacosa took no part.

In Case Nos. 57 and 58: Order affirmed, with costs, and certified question answered in the affirmative. Opinion by Chief Judge Wachtler. Judges Alexander, Tine and Hancock concur. Judge Mollen dissents in part and votes to modify in an opinion. Judges Simons, Kaye and Bellacosa took no part.

Decided April 4, 1989

APPENDIX B

Appellate Division Order
(April 14, 1988)

At a term of the Appellate Division of the Supreme Court held in and for the First Judicial Department in the County of New York, on April 14, 1988

Present-Hon. Theordore R. Kupferman, **Justice Presiding**
Sidney H. Asch
Ernst H. Rosenberger
Betty Weinberg Ellerin
George Bundy Smith, **Justices.**

.....x

Mindy Hymowitz,

Plaintiff-Respondent,

-against-

Eli Lilly and Company, Abbott Laboratories, The Upjohn Company and E. R. Squibb & Sons, Inc.,

Defendants-Appellants. 31981

-and-

Merck & Co., Inc., Ayerst Laboratories, a division of American Home Products Corp., and Winthrop Laboratories, a division of Sterling Drug, Inc.,

Defendants,

Attorney General of the State of New York,
Intervenor-Respondent

.....x

An appeal having been taken to this Court by the defendants-appellants from an order of the Supreme Court, New York County (Ira Gammerman, J.), entered on July 21, 1987,

And said appeal having been argued by Roy G. Weatherup of counsel for appellant E.R. Squibb & Sons, Inc., by Russel H. Beatie, Jr. of counsel for appellant Eli Lilly and Company, by Robin J. Stout of counsel for appellant The Upjohn Company, by Karl E. Seib, Jr. of counsel for appellant Abbott Laboratories, by Paul D. Rheingold of counsel for respondent, by Andrea Green of counsel for intervenor-respondent, and a brief as amicus curiae having been submitted by Joseph M. Costello on behalf of All Putter Company, Inc.; and due deliberation having been had thereon,

It is unanimously ordered that the order so appealed from be and the same hereby is affirmed for the reasons stated by Ira Gammerman, J., without costs and without disbursements.

ENTER:

HAROLD J. REYNOLDS

Clerk.

APPENDIX C

Appellate Division Order and Opinion
(April 14, 1988)

At a term of the Appellate Division of the Supreme Court held in and for the First Judicial Department in the County of New York, on April 14, 1988

Present-Hon. Theordore R. Kupferman, Justice Presiding
Sidney H. Asch
Ernst H. Rosenberger
Betty Weinberg Ellerin
George Bundy Smith, Justices.

Elizabeth Tigue, Barbara Tigue, Sayre Margolies, as Administratrix of the Estate of Myrna Margolies,

Plaintiffs-Respondents,

-against-

E.R.Squibb & Sons, Inc., Abbott Laboratories, Boyle & Company Pharmaceuticals, Merck Sharp & Dohme, a Division of Merck & Co., Inc., Rexall Drug Company, William H. Rorer, Inc. and The Upjohn Company,

Defendants-Appellants,

Amfre-Grant Inc., a Subsidiary of Ormont Drug & Chemical Co., Inc., Carnrick Laboratories, a Division of G.W.Carnrick Co., Cole Pharmacal Company, Inc., Kremers-Urban Company, and Jerome Schneider, M.D.

Defendants.

31980

An appeal having been taken to this Court by the defendants-appellants from an order of the Supreme Court, New York County (Ira Gammerman, J.), entered

on July 23, 1987, which denied appellants' motions, pursuant to CPLR 3212 for summary judgment dismissing the plaintiffs' complaint.

And said appeal having been argued by John L. McGoldrick of counsel for appellant Abbott Laboratories, by A.Edward Grashof of counsel for appellant Rexall Drug Company, by Jay P. Mayesh of counsel for appellant The Upjohn Company, by William K.Dodds of counsel for appellant Boyle & Company Pharmaceuticals, by Joseph DiBenedetto of counsel for appellant Rorer Pharmaceutical Corp., f/k/a William H. Rorer, Inc., by Roy G. Weatherup of counsel for appellant E.R.Squibb & Sons, Inc., by Theodore V.H. Mayer of counsel for appellant Merck Sharp & Dohme, a Division of Merck & Co., Inc., and by Paul D. Rheingold of counsel for respondents; and due deliberation having been had thereon, and upon the memorandum decision of this Court filed herein.

It is unanimously ordered that the order so appealed from be and the same hereby is affirmed, without costs and without disbursements.

ENTER:

HAROLD J. REYNOLDS
Clerk.

Kupferman, J.P., Asch, Rosengerger, Ellerin, Smith, JJ.

31980 Elizabeth Tigue, et al.,
Plaintiffs-Respondents, P.D. Rheingold

-against-

E.R. Squibb & Sons, Inc., et al.,

Defendants-Appellants,

J.L.McGoldrick
A.E.Grashof
J.P.Mayesh
W.K.Dodds
J.DiBenedetto
R.G.Weatherup
T.V.H.Mayer

Amfre-Grant Inc., etc., et al.,
Defendants.

Order, Supreme Court, New York County (Ira Gammerman, J.), entered July 23, 1987, denying the motions of defendants Rexall, Upjohn and Abbott, pursuant to CPLR 3212, for summary judgment dismissing the plaintiffs' complaints, unanimously affirmed, without costs.

Seven drug manufacturers appeal from a well-reasoned determination which denied exculpation based on their claim that they were not the manufacturer of the drug known as diethlystilbestrol (DES), allegedly ingested by the mothers of the plaintiffs. The history of DES is well documented in a previous opinion of this court, *Bichler v Eli Lilly and Co.*, 79 AD2d 317.

The underlying problem presented is which of the many manufacturers of this unpatented drug should be held culpable, where it cannot be definitively determined which company manufactured the pills ingested by the plaintiffs' mothers.

In the 1987 cumulative supplement to his treatise, 1 NY Products Liability Sec. § 107, Michael Weinberger succinctly analyzes the present state of the law under the heading "Enterprise Liability":

In Bichler v. Eli Lilly & Co.,* the Court of Appeals affirmed a plaintiff's verdict, which was based on a concerted action theory. However, the Court did not decide the validity of a cause of action based on concerted action in DES cases. The court stated that because defendant did not object to the trial court's instructions on concerted action, this theory became the law of the case, and was not preserved for appellate review. Hence, the court took no position on the question of whether New York recognizes a cause of action based on concerted action.

In a later related DES case, the Court of Appeals again took no position on whether the theory of concerted action (or other related theories) should be adopted in DES cases. The court held only that the Bichler jury finding of concerted action was not entitled to collateral estoppel effect, because the issue of concerted action was not actually contested in the trial judge's jury charge in the earlier case.** Therefore, New York still has no position on whether a cause of action in DES cases can be based on concerted action.

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* 9.50 Bichler v. Eli Lilly & Co., 55 NY2d 571, 450 NYS2d 776, 436 NE2d 182 (1982)

** 9.60 Kaufman v. Eli Lilly & Co., 65 NY2d 449, 492 NYS2d 584, 482 NE2d 63 (1985).

As noted by Justice Gammerman, the law in this Department clearly recognizes the concerted action theory. *Bichler v. Eli Lilly & Co., supra*, 79 AD2d at 328-29. There is, however, still a question of whether exculpation is available to those drug manufacturers who can clearly establish that they could not have been the purveyor of the drug to a particular plaintiff, which question is also significant in the many other DES cases presently pending in the courts. For example, it was testified that hard, small, white tablets were ingested by Mrs. Tigue. It is contended that because a different colored pill was marketed, there is no liability. Another defendant contends that it sold only to its licensed franchisees and, therefore, inasmuch as the pills in question were purchased at a specific pharmacy which was not the one of its franchisees, there should be no liability. Another defendant postulates that it did not sell in the East and so could not have been the purveyor to these plaintiffs. Still another defendant contends that it did not market DES for pregnancy-related purposes.

Basic to any determination is the question of whether exculpation should be permitted at all. However, in view of the fact that the Court of Appeals has, in two instances, left the question of concerted action open, we should now permit a complete trial record to be developed, so that when the matter is finally determined, there will be no question as to the factual details.

Order filed.

APPENDIX D

Appellate Division Order
(April 14, 1988)

At a term of the Appellate Division of the Supreme Court held in and for the First Judicial Department in the County of New York, on April 14, 1988

Present—Hon. Theordore R. Kupferman, Justice Presiding
Sidney H. Asch
Ernst H. Rosenberger
Betty Weinberg Ellerin
George Bundy Smith, Justices.

Jane Dolan, et al., Plaintiffs-Respondents, -against- Eli Lilly & Company, E.R.Squibb & Sons, Inc., The Upjohn Company and Winthrop-Breon Laboratories, Defendants-Appellants. (and other actions)	31982 -83-84

Appeals having been taken to this Court by the above-named appellants from an order of the Supreme Court, New York County (Ira Gammerman, J.), entered on or about October 14, 1987, an order of said court entered on or about October 16, 1987, and an order of said court, entered on September 29, 1987,

And said appeals having been argued by Russel H. Beatie, Jr. of counsel for appellant Eli Lilly & Company,

by Roy G. Weatherup of counsel for appellant E.R.Squibb & Sons, Inc., by Jay P. Mayesh of counsel for appellant The Upjohn Company, and by Alfred S. Julien and Herman Schmertz of counsel for respondents; and due deliberation having been thereon,

It is unanimously ordered that the three orders so appealed from be and the same hereby are affirmed, without costs and disbursements

ENTER:

HAROLD J. REYNOLDS
Clerk.

APPENDIX E

Opinion of Supreme Court, New York County
(July 16, 1987)

SUPREME COURT : NEW YORK COUNTY
IAS : PART 27

MINDY HYMOWITZ.

Plaintiffs,

-against-

ELI LILLY and COMPANY, WINTHROP LABORATORIES, a division of STERLING DRUG, INC., THE UPJOHN COMPANY, E. R. SQUIBB & SONS, and AYERST LABORATORIES, a division of AMERICAN HOME PRODUCTS, CORP.,

Defendants.

INDEX NO. 24767-86

GAMMERMAN, J.:

In this pharmaceutical product liability action, plaintiff Mindy Hymowitz alleges that she developed cancer as a result of prenatal exposure to diethylstilbestrol ("DES"), a synthetic estrogen taken by her mother in 1954 during pregnancy to prevent possible miscarriage.

Plaintiff was born on December 11, 1954. The cancerous condition for which plaintiff seeks damages allegedly appeared in 1979. Under the statute of limitations then applicable (CPLR 208, 214) plaintiff was barred from commencing suit in December, 1975 (three years after reaching the age of majority). Plaintiff brings this action, however, under the provisions of 1986 revival statute (L. 1986 ch. 682 §4).

Plaintiff moves pursuant to CPLR 3212 to strike affirmative defenses raised by some defendants challenging the constitutionality of the revival statute and alleging that the action is time barred under the statute of limitations otherwise applicable.

Defendants Eli Lilly and Co. ("Lilly") [sic] Abbott Laboratories ("Abbott") and The Upjohn Company ("Upjohn") seek summary judgment and dismissal of the complaint as barred by the statute of limitations absent the availability of the allegedly unconstitutional revival statute.

Defendant E.R. Squibb & Sons ("Squibb) opposes the relief sought by plaintiff and contends that before the issue of the constitutionality of the revival statute is determined further discovery is required on the issue of whether such extraordinary circumstances exist in this case to justify invocation of the statute which Squibb also contends is unconstitutional. (Squibb further urges that discovery is needed to determine whether plaintiff can identify the manufacturer of the DES actually taken by her mother).

The revival portion of the 1986 tort reform legislation provides that actions seeking damages for personal injury, property damage or death caused by the latent effects of exposure to five substances (DES, asbestos, tungsten-carbide, chlordane and polyvinyl-chloride) that were time barred or dismissed, as of the effective date of the statute, may be instituted " . .within one year from the effective date of this act." The statute was passed on July 1, 1986 and was signed by the Governor on July 30, 1986.

In addition to the revival provision for the five specified substances (§4), the new tort reform legislation adopted a general discovery based statute of limitations

for injuries caused by latent effects of exposure to any substance (CPLR 214-c(2)). Under subsection 2, a victim may assert a cause of action within three years from the date the injury was or should have been discovered.

The provision for revival of claims (§4) and the discovery based statute of limitations (2) were intended by the Legislature to remedy the perceived injustice caused by the application of CPLR §§214, 208, (the exposure based statute of limitations) and to provide legal recourse for injuries caused by latent effects of toxic substances. Both provisions were enacted to remedy the failure of the old statute to recognize that such injuries may not appear until years after exposure, long after the expiration of the period within which actions may be instituted.

Legislative history indicates that the five named substances were distinguished from other toxic substances (2) as a result of compromise between the Assembly (which had voted to permit revival for all toxic substances) and the Senate which wanted to limit revival. The Legislature ultimately limited revival based upon the existence of an identifiable group affected and the resulting ability to predict the future costs of such revival. The Legislature was apparently concerned that under a broader revival statute, the large number of unknown victims would create unpredictable risks and costs.

Defendants challenge the revival statute on equal protection and due process grounds, arguing that the statute is the result of an arbitrary and irrational political arrangement arrived at without rational guidelines of scientific certainity or public necessity. Defendants further argue that the legislative concern for limiting the number of potential claimants and costs is not related to the ostensible objective of the legislation, i.e. to allow

victims of latent injuries to maintain actions. Defendants contend that the revival provision must be stricken on equal protection grounds, as an underinclusive random penalty without scientific basis, on five arbitrarily chosen substances and their manufacturers. It is contended that the prior exposure statute of limitations or the new three year discovery based provision would be more than adequate for victims of the five specified substances.

Defendant Lilly urges that generally, chemical injury claims accrue at the time of exposure (here, in utero). Under the three year exposure based statute of limitations (tolled to the age of majority) claimants could bring suit until age 21. Lilly contends that most DES patients develop cancer by age 19; and therefore, their claims would not be time barred before becoming aware of their injuries.

Defendants also claim a violation of the due process clause, in that the statute constitutes an arbitrary deprivation of the substantive property right to rely upon the absence of claims. Defendants assert that dismissal (or the passage of the applicable time bar) gives rise to substantive property rights which as a general rule, may not be abrogated and that the exceptional circumstances to permit revival are not present (*see Gallewski v. H. Hentz & Co.*, 301 N.Y. 164).

Based upon the impact upon what they allege are substantive or property rights, defendants urge the applicability of strict scrutiny or an intermediate standard of review rather than a rational basis examination.

As a general rule, state statutes of limitation reviving time barred actions are not violative of due process. Statutes of limitation represent a public policy statement with respect to the privilege to litigate. "[T]he history

of pleas of limitations shows them to be good only by legislative grace and to be subject to a relatively large degree of legislative control" (*Chase Securities Corp. v. Donaldson*, 325 U.S. 304, 314). The expiration of the applicable time period does not eliminate a cause of action but rather, suspends the court's power to grant a remedy (*Hulbert v. Clark*, 125 N.Y. 295). In other words, statutes of limitation relate to the availability of a remedy and not to the destruction of any fundamental right.

In the past, New York courts have upheld the power of the state legislature to extend or revive time barred claims. In *Gallewski v. H. Hentz & Co.* (301 N.Y. 164, 174), the court found that a revival statute is not necessarily void as a taking of property without due process. The court stated that "[T]he legislature may constitutionally revive a personal cause of action where the circumstances are exceptional and are such as to satisfy the court that serious injustice would result to plaintiffs not guilty of any fault if the intention of the legislature were not effected."

In *McCann v. Walsh Construction Co.*, (282 A.D. 444, *aff'd*, 306 N.Y. 906) the court found that the legislature acted within the limits of the Constitution in extending the time period within which victims of caissons disease could seek redress. The legislature sought to remedy the injustice caused to victims of a disease which in many cases did not produce symptoms until after the period for filing Workmen's Compensation claims has passed. The court found that under the circumstances, the legislature, by extending the time within which to institute a claim, was merely complying with the simple demands of justice.

A similar due process challenge was raised by manufacturers of Agent Orange regarding the constitutionality of the recent statute extending the time within which victims of dioxin could sue in New York (CPLR 214-b). There, as here, defendants challenged the law on the round that it permitted commencement of actions already time barred under the New York statute of limitations otherwise applicable for injuries caused by toxic chemicals. In approving the proposed settlement of the Agent Orange litigation, the Court (Weinstein, J.) rejected defendants' federal and state constitutional challenges to revival of otherwise time barred claims by the New York legislature (*In Re Agent Orange Product Liability Litigation*, 597 F. Supp. 740 [E.D.N.Y. 1984]).

Here, as in *Gallewski, McCann* and the *Agent Orange* case, the legislature, in reviving time barred causes of action, expressed the public policy of giving preference to plaintiff's privilege to litigate over defendants' protection from stale or time barred claims. The issue raised is whether there is a reasonable connection between the revival statute and the promotion of a legitimate state interest, here, health, safety and welfare (*Nettleton Co. v. Diamond*, 27 N.Y.2d 182, 193). In examining the constitutionality of statutes generally, the court must bear in mind the strong presumption that the legislature investigated the problem it addressed and discovered the need for the legislation passed (*Matter of Taylor v. Sise*, 33 N.Y.2d 357). The court must determine: (1) whether the legislature was acting in pursuit of permissible state objectives and, if so; (2) were the means adopted reasonably related to the accomplishment of those objectives (*Montgomery v. Daniels*, 38 N.Y.2d 41, 54).

Here, the legislature acted within permissible objectives relating to health, safety and welfare by reviving causes of action based upon latent effects of exposure to toxic substances.

Where a question of what the facts establish is raised, the court should accept the opinion of the legisature *Lincoln Bldg. Assoc. v. Barr*, 1 N.Y.2d 413, 415, *app dism* 355 U.S. 12, *citing Old Dearborne Co. v. Seagram Corp.*, 299 U.S. 183, 196). In enacting the challenged statute, the legislature expressed the view that victims of the latent effects of certain toxic substances were being denied legal recourse by the automatic application of the exposure based statute of limitations often enough to justify an exception to its general application. A reasonable relationship exists between the reform and the objective of remedying the defects or inequities under the prior statute of limitations. There is considerable support for the position upon which the legislature acted: the need to provide a forum for innocent victims who might otherwise be time barred before becoming aware of their injuries. Indeed, this case is illustrative of that need. That studies or data may refute the legislative conclusions is not dispositive. As the Court of Appeals stated:

> [t]he judiciary, however is not called on to weigh the relative worth of data or arguments which may be marshaled on either side as to the wisdom of determinations made by the Legislature in the realm of policy. 'Whether the enactment is wise or unwise, whether it is based on sound economic theory, whether it is the best means to achieve the desired result, whether, in short, the legislative discretion within its prescribed limits should be exercised in a particular manner, are matters for the

> judgment of the legislature, and the earnest conflict of serious opinion does not suffice to bring them within the range of judicial cognizance'.

(*Montgomery v. Daniels,* 38 N.Y.2d 41, 53, *quoting Chicago, Burlington & Quincy RR Co. v. McGuire,* 219 U.S. 549, 569.)

Given the substantial degree of legislative consideration to the need for the challenged tort reform, it would be inappropriate to express an opinion regarding the factual predicate for the statute, its philosophical justification or the wisdom of its enactment (*see Montgomery v. Daniels, id.* at 53). In addition, staleness of claims based on the loss of evidence over time is not of significance. Defendants have been litigating similar non-time barred DES cases for years.

Many of the same concepts relevant to the due process analysis are applicable to defendants' equal protection challenge. Defendants argue that the revival statute is underinclusive; it arbitrarily, without scientific basis singles out five substances for the additional burden of revival while excluding other toxic chemicals which cause latent injuries; it discriminates against out-of-state manufacturers; and it denies to defendant the protection of new Article 16 and the 2 discovery based statute of limitations.

Equal protection essentially requires that all persons similarly situated should be treated alike (*Plyler v. Doe,* 457 U.S. 202). As with the due process argument, the court must determine the appropriate standard of review. When social legislation relating to the public health is challenged, as here, the standard of review is rather narrow. The revival statute, contrary to defendants' contentions, does not classify on the basis of a suspect

(or quasi-suspect) class or impair a fundamental right and therefore a strict scrutiny standard is not applicable. The legislation must be upheld if the challenged classification (targeting the five substances to the exclusion of other toxic chemicals causing latent injuries) is rationally related to a legitimate state purpose (*Western & S. Ins. Co. v. Board of Equalization*, 451 U.S. 648, 657; *Trump v. Chu*, 65 N.Y.2d 20, 25).

Under the rational basis analysis, if any conceivable facts support the classification, there is no violation of the equal protection clause. A law may not be arbitrary or irrational and must be reasonably related to some "manifest evil" which need only be "reasonably apprehended." It is only as a last resort that courts will invalidate legislation as unconstitutional (*Maresca v. Cuomo*, 64 N.Y.2d 242, 250). Further, the stated purpose justifying the statute need not be its primary purpose (*McGinnis v. Royster*, 410 U.S. 263, 276) and the court may even hypothesize the motives of the legislature to discern any conceivable legitimate goal furthered by the provision being attacked (*Maresca v. Cuomo, supra*, at 251, *quoting Weinberger v. Salfi*, 422 U.S. 749, 780).

Defendants' objection to the distinctions drawn by the legislature between the five materials and other toxic substances is based partly upon the different treatment accorded the two groups under the 1986 tort reform bill. Defendants point to the traditional burden of revival and the apparent inapplicability of Article 16 to the revival section. Examination of the provision (as it relates to DES cases) and the legislative history, reveals significant reasons to justify those distinctions, based upon the perceived realities of the latent effects of exposure to the five substances, the ability to ascertain a finite group of potential claimants and consequently to predict with some accuracy the economic costs of

revival. Given the reasonable basis for the distinctions drawn by the legislature, the alleged lack of scientific precision involved in drawing the line for revival may be disregarded. Here, the statutory classification does not result in such disparate treatment as to be arbitrary, irrational or invidiously discriminatory (*see Dandridge v. Williams*, 397 U.S. 471; *see also Parker 86th Associates v. City of New York*, 93 A.D.2d, 388, 394, *aff'd* 59 N.Y.2d 986).

The legislation and the challenged classification passes constitutional muster under a rational basis test or even under the more demanding intermediate standard ("somewhere along the sliding scale between strict scrutiny. . . and rational basis" (*Montgomery v. Daniels*, 38 N.Y.2d 41, 61)). It cannot be said that the legislature acted unreasonably in selecting the five substances for special treatment. The constitution is not offended merely because the classification is not made with mathematical or scientific exactitude or because in practice it results in some inequity (*Dandridge v. Williams, supra* at 485; *Montgomery v. Daniels, supra,* at 63). In enacting reform legislation, the legislature is permitted to proceed one step at a time and to address the part of the problem that appears most serious (*Williamson v. Lee Optical Co.*, 348 U.S. 483, 489; *Montgomery v. Daniels, supra*, at 62).

Seen in its most fundamental light, defendants object to the fact that the line drawn by the legislature in enacting tort reform includes them. Whenever the legislature draws such a line some must be included, some excluded. As long as the line drawn is reasonable, the decision as to where to draw it is left to the legislature and not the judiciary (*Village of Belle Terre v. Boraas*, 416 U.S. 1, 8; *Montgomery v. Daniels*, 38 N.Y.2d 41).

Squibb maintains that a theory of liability under which a claimant may maintain an action without identifying the particular manufacturer of the DES taken by her mother is unconstitutional. Squibb contends that under the separation of powers doctrine such a radical restructuring of traditional tort law must be left to the legislature. Based upon a mistaken belief that causation need not be shown under the challenged theories, it argues that absent causation plaintiff lacks standing and this court is powerless to provide a remedy.

Defendant's contentions lack merit and wholly fail to meet the stringent burden to establish unconstitutionality.

Accordingly, plaintiff's motion to strike the affirmative defenses challenging the revival statute as unconstitutional and alleging that this action is time barred, is granted.

Defendants' cross-motion for summary judgment dismissing the complaint as barred by the statute of limitations are denied.

This constitutes the decision and order of the court.

Dated: July 16, 1987

/S/ IRA GAMMERMAN

J.S.C.

F I L E D
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COUNTY CLERK'S OFFICE
NEW YORK

APPENDIX F

Opinion of Supreme Court, New York County
(July 16, 1987)

SUPREME COURT : NEW YORK COUNTY
IAS : PART 27

..... x

ELIZABETH TIGUE, BARBARA TIGUE, SAYRE MARGOLIES, as Administratrix of the Estate of MYRNA MARGOLIES,

Plaintiffs,

-against-

E.R. SQUIBB & SONS, INC., ABBOTT LABORATORIES; AMFRE-GRANT, INC., a Subsidiary of ORMONT DRUG & CHEMICAL CO., INC.; BOYLE & COMPANY PHARMACEUTICALS; CARNRICK LABORATORIES, Division of G. W. CARNRICK CO.; COLE PHARMACAL COMPANY, INC.; KREMERS-URBAN COMPANY, ELI LILLY and COMPANY; MERCK SHARP & DOHME, Division of MERCK & CO., INC.; REXALL DRUG COMPANY; WILLIAM H. RORER, INC.; THE UPJOHN COMPANY, and JEROME SCHNEIDER, M.D.

INDEX NO. 3838-76

Defendants.

..... x

GAMMERMAN, J.:

Defendants Rexall Drug Company ("Rexall"), The Upjohn Company ("Upjohn") and Abbott Laboratories, ("Abbott") move pursuant to CPLR 3212 for summary judgment dismissing the complaint based upon the

conceded inability of plaintiffs to identify the particular manufacturer of the drug, diethylstilbestrol, ("DES") to which they were allegedly exposed. Defendants contend that the right to recover on collective, non-identification or concerted action theories of liability has not been established in New York and urge the court to reject adoption of such theories. Defendants further contend that if concerted action is a viable basis of liability, it should not be applicable in a DES case. The motions are consolidated for disposition.

Plaintiffs seek to recover for injuries allegedly sustained by Elizabeth Tigue and Myrna Margolies (now deceased) as a result of the ingestion of DES by their mothers. Sayre Margolies proceeds on behalf of her daughter Myrna who died in 1977 at age 23, from clear cell adenocarcinoma of the cervix and vagina, a rare form of cancer in young women, associated with prenatal exposure to DES. Plaintiff Elizabeth Tigue was diagnosed as having vaginal adenosis, a pre-cancerous condition associated with DES exposure, in which glandular tissue normally found in the cervix is found in the vagina. Plaintiffs' complaints allege breach of warranty, negligence, strict liability, res ipsa loquitur, concerted action and aiding and abetting-strict liability.

Historical Background:

DES is a synthetic hormone that duplicates the function of estrogen, a female sex hormone naturally present in women and, in lesser amounts, in men. Estrogen is essential for female sexual development and reproduction. DES was first synthesized in 1937 by British medical researchers. The drug was never patented, and thus, could be produced and marketed in the United States by any company obtaining Food

and Drug Administration ("FDA") approval of a New Drug Application ("NDA").

By 1940 ten drug companies had filed NDAs requesting approval to produce and market DES for treatment of menopause, senile vaginitis, gonorrheal vaginitis and suppression of lactation. None of the conditions for which this initial approval was sought related to pregnancy. These filings were rejected by the FDA, it determining that the review process would be facilitated by the pooling of clinical data produced by the drug companies into a master file which would form the data base for the FDA decision. In 1941, twelve pharmaceutcial companies formed the "Small Committee"[1] to pool this clinical data for submission to the FDA. The joint clinical data was incorporated in each company's resubmitted NDA and in September, 1941, FDA approval was obtained for the use of DES. The Small Committee was thereafter disbanded.

In 1947 and 1948 a number of drug manufacturers filed supplemental NDAs for authorization to market DES, now for the treatment of certain pregnancy disorders relating to spontaneous abortion or fetal death. The dosage proposed for this treatment was many times stronger than the dosage previously approved in 1941. The supplemental applications were primarily based upon studies by two independent researches on the role of hormones in pregnancy. The researchers reported that the administration of additional estrogen in certain high

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[1]The twelve companies were: Abbott; Armour Laboratories; Ayerst, McKenna & Harrison, Ltd.; Geo. A. Breon & Co., Inc.; Charles E. Frost & Co.; Eli Lilly & Co.; Merck & Co., Inc.; Sharp & Dohme, Inc.; E.R. Squibb & Sons; Upjohn Winthrop Chemical Company; and John Wyeth & Brothers, Inc. (Affidavit of Don Charles Hines, M.D. at p. 8).

risk pregnancies appeared to reduce the risk of miscarriage. FDA approval for use of the drug in pregnancy was then given.

Lack of Product Identification:

The fundamental issue raised here (and the major problem facing these and many other plaintiffs in these DES cases) is their inability to identify the manufacturer of the DES taken by the mothers of the injured women and, thus, to directly connect the injury to a particular defendant.

The DES taken by pregnant women was produced under a chemically identical formula and usually manufactured and prescribed generically. Apparently, many drug companies cannot locate or have failed to keep records of their DES market activity. Although that market was dominated by a small number of companies, entry and exit from the market was fluid and it is estimated that between 94 and 300 pharmaceutical companies manufactured or marketed DES from 1947 to 1971.

Injuries caused by prenatal exposure to DES appear many years later. Over time, the ability of a plaintiff to identify the manufacturer is, obviously, greatly reduced. The memories or records of those who could assist in identifying the manufacturer (parents, physicians, pharmacists and drug companies) fade or disappear.

Prior Holdings:

In this state, the general rule is that a plaintiff has the burden of proof on product identification (*Morrissey v. Conservative Gas Corp.*, 285 A.D. 825 [1955], *aff'd* 1 N.Y.2d 741 [1956]). However, several non-

identification or collective liability theories have been proposed and in some cases adopted, to deal with cases in which the manufacturer of a product cannot be identified.

In *Bichler v. Lilly & Co.*, (79 A.D.2d 317 [1st Dept. 1981], *aff'd*, 55 N.Y.2d 571 [1982]), a theory of concerted action liability was the basis of recovery even though the defendant was not identified as the manufacturer of the particular DES taken by the plaintiff's mother. Indeed in *Bichler*, the jury found that the plaintiff had not established that Lilly manufactured the DES taken by her mother.

Two theories of concerted action were submitted to the jury: concerted action by implied agreement and concerted action by substantial assistance. The jury was instructed that concerted action by agreement could be inferred from evidence of consciously parallel actions, that such consciously parallel action could be the basis of a finding that the drug companies had impliedly agreed to market DES for pregnancy use without first testing the drug on pregnant mice. The trial court's charge with respect to concerted action by substantial assistance permitted the jury to find that the failure to test DES on pregnant mice by defendant Lilly substantially aided or encouraged other companies (including, presumably, the company that marketed the DES taken by plaintiff's mother) to market without appropriate testing.

The jury found that Lilly had acted in concert, that the failure to test was wrongful and that the injurious effects of DES were foreseeable. On appeal to the Appellate Division, defendant argued that the trial court's concerted action charge was erroneous, an argument that the court addressed on its merits.

The Appellate Division found sufficient evidence to support the jury's findings and, in effect, adopted the concerted action theory of liability charged by the trial court. When *Bichler* reached the Court of Appeals, a determination was made that Lilly had failed to properly except to the trial court's charge on concerted action and concerted action liability was applicable only as the law of the case. The Court concluded that there was adequate evidence to support concerted action liability by conscious parallelism or substantial assistance. The Court of Appeals (unlike the trial court and the Appellate Division) based its finding solely on events beginning in 1947 (formation of identical chemical standards, marketing DES without testing on pregnant mice, reliance upon the same studies to support supplemental NDAs) and indicated that the 1941 collaboration to secure approval for non-pregnancy use, had no bearing upon concerted action relating to the 1947 supplemental NDA for pregnancy use (*Bichler v. Lilly & Co.*, 55 N.Y.2d 571, 585, n.7).

In *Kaufman v. Lilly & Co.*, (65 N.Y.2d 449, 456, [sic] the court stated: ". .we expressed no view in *Bichler* and, express none now, on which the proposed theories-concerted action, alternative liability, enterprise liability or market share liability - if any, should be adopted in this or similar DES cases (*see, Bichler v. Lilly & Co., supra*, at p. 580, n.5). The question is still an open one in New York."

Discussion:

Defendants correctly contend that the applicability of the various "collective liability" theories (including concerted action) to DES fact patterns has not been finally ruled upon by the Court of Appeals. Nevertheless, the First Department clearly recognized and expressly

adopted the concerted action theory for DES cases (*Bichler v. Lilly & Co.*, 79 A.D.2d 317; *Kaufman v. Lilly & Co.*, 99 A.D.2d 695; *see, Carrao v. Heitler*, 117 A.D.2d 308, 313).

Since plaintiffs, at least in this Department, may proceed on a collective or concerted action liability theory, the inability to identify the actual manufacturer of the DES taken by Mrs. Tigue and Mrs. Margolies is not fatal. Plaintiffs' factual allegations to support a finding of concerted action are substantially the same as those pleaded in *Bichler* and clearly state a viable cause of action for concert by agreement or substantial assistance.

As in *Bichler,* plaintiffs contend that a finding of concert by conscious parallelism or substantial assistance may be supported based upon the formation of identical chemcial standards for DES in pregnancy, the marketing of the drug without prior testing on pregnant mice and the drug companies' reliance upon the same studies in supplemental NDAs. Plaintiffs also rely on defendants' activities leading to the FDA approval for non-pregnancy use based upon the contention that their supplemental NDAs relied upon the earlier filing. Whether the requests for approval of DES for use in pregnancy relied upon the earlier filings presents an issue of fact which cannot be determined on a motion for summary judgment. Similarly, defendant's claims that the actions by the drug companies in gaining FDA approval of DES (whether for non-pregnancy or pregnancy use) and their actions with regard to the manufacture, marketing and distribution of DES for use in pregnancy constitute concerted action sufficient to impose liability are questions for the trier of fact.

In addition, plaintiffs apparently seek to impose industry wide liability based upon wrongful failure to test and subsequent generic marketing and dispensing of DES. Plaintiffs' basic theory is that "but for the development, manufacture, distribution and sale of DES by the defendants, plaintiffs would not have suffered the injuries which they have suffered."

Plaintiffs contend that under their "but for" analysis, in addition to concert, they would be permitted to recover under various non-identification theories: enterprise liability (*Hall v. E. I. DuPont de Nemours & Co.*, 345 F.Supp. 353 [EDNY] 1972); alternative liability; market share liability (*Sindell v. Abbott Laboratories*, 163 Cal. Rptr. 132, 607 P. 2d 924) *cert. denied*, 449 U.S. 912; risk contribution (*Collins v. Eli Lilly & Co.*, 116 Wis. 166, 342 N.W.2d 37 *cert. denied*, 469 U.S. 826).

This Court declines to rule at this time on the applicability to DES cases of each of the various theories of liability (in addition to concerted action), which are not specifically pleaded but are raised in response to defendants' motions. The only question raised on the motions before this court is whether defendants may be held liable absent product identification and the answer is yes.

Claims of Exculpation:

Defendants Rexall and Upjohn contend that under any collective liability theory, a defendant who can establish that its product could not have caused plaintiff's injury may exculpate itself from liability. While exculpation may be theoretically possible (certainly under market share liability), even if the product of a particular manufacturer could be excluded a defendant may bear legal responsibility based on joint activity,

encouragement or assistance in bringing a harmful product into the stream of commerce.

Constitutional Attack:

Rexall further contends that any theory of liability (including judicially established tort doctrines) under which liability may be imposed without "causation-in-fact", presumably product identification, is unconstitutional as an excessive burden on interstate commerce and violative the due process and equal protection clauses. Further, it argues, that imposing market share and enterprise liability frustrate expressed federal policies regarding the marketing of prescription drugs and thus violate the supremacy clause.

Defendant Rexall's due process challenges are unpersuasive. Under the various theories discussed above, the requirement of traditional product identification is merely relaxed based on a finding that each defendant by its tortious behavior caused or contributed to plaintiff's injuries. Under these theories, liability may be premised upon the tortious behavior of each defendant, whose adherence to a course of conduct resulting in an unsafe standard, perpetuates the standard.

Fundamentally, imposition of liability absent product identification is based on policy grounds. As a matter of equity, the tortfeasor (who is in the best position to absorb the cost and to take the precautions) rather than the innocent victim, should bear the cost of injury. Defendants can be held responsible for wrongful conduct or omissions that result in placing a generic/fungible harmful product on the market.

Rexall's equal protection challenge amounts to no more than a fairness argument which does not rise to constitutional proportions. Equal protection is not

synonymous with absolute equality (*see Dandridge v. Williams*, 397 U.S. 471; *People v. Parker*, 41 N.Y.2d 21; *Parker 86th Associates v. City of New York*, 93 A.D.2d 388, *aff'd*, 59 N.Y.2d 986).

Rexall's federal preemption claim also lacks merit. "The criteria for determining whether there has been federal preemption are (1) the pervasiveness of the federal regulation, (2) the dominance of the federal interest, (3) the federal and state objectives to be obtained, and (4) the existence of actual conflict between the state and federal statutes, including whether the state law is an obstacle to the purposes and objectives of Congress" (*Pharmaceutical Soc. of State of New York v. Lefkowitz*, 586 F.2d 953, 958 [2d Cir., 1978]). Application of these criteria precludes a finding of federal preemption. the primary objective of the federal law is controlling product safety and efficacy (*id.*, p. 958). The objective of the proposed theories of recovery is basic fairness, to provide a remedy to the innocent victims of wrongdoers.

Rexall contends that the imposition of liability without product identification burdens interstate commerce, by increasing the cost of products, reducing availability and limiting sales by discouraging development of new drugs, and by generally increasing the cost of doing business thereby precluding entry into the pharmaceutical business.

In determining whether there is an undue burden on interstate commerce, the test is whether ". . .the burden on [interstate] commerce is clearly excessive in relation to the putative local benefits " (id at 957, *quoting Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142). Here, the local benefit is providing a forum to innocent victims of alleged wrongdoing by relaxing the traditional

product identification requirement in tort law. Clearly, a legitimate state interest is furthered. While adoption of a non-identification theory of liability could conceivably burden interstate commerce to the extent that the cost of such increased liability would be passed on to consumers through higher prices, ". . .[n]ot every exercise of local power is invalid merely because it affects in some way the flow the commerce between the States" (*Great Atlantic & Pacific Tea Co. v. Gottrell*, 424 U.S. 366, 371). Rexall has failed to demonstrate that the burden here would be clearly excessive compared to the benefit. Therefore, the commerce clause challenge also must fail.

Accordingly, defendants' motions for summary judgment dismissing the complaint are denied, and the matter is set down for trial on September 30, 1987.

Dated: July 16, 1987

/S/

J.S.C.

IRA GAMMERMAN

APPENDIX G

Order of Supreme Court, New York County
(September 23, 1987)

At an individual Assignment Part 26 of the Supreme Court of the State of New York, held in and for the County of New York, at 60 Centre Street, New York, New York on September 23, 1987.

Present:

HONORABLE IRA GAMMERMAN, Justice.

.....x

JANE DOLAN,

Plaintiff,

-against-

ELI LILLY & COMPANY, E.R. SQUIBB & SONS, INC., THE UPJOHN COMPANY, and WINTHROP-BREON LABORATORIES,

Defendants.

Index No. 23999/86 (Assigned to Justice Gammerman)

ORDER

.....x

Defendant The Upjohn Company ("Upjohn"), having moved this Court for an Order pursuant to Rule 3212 of the Civil Practice Law and Rules granting Upjohn summary judgment; and defendant E.R. Squibb & Sons, Inc. ("Squibb") having cross-moved pursuant to Rule 3212(e) of the Civil Practice Law and Rules for an Order granting partial summary judgment in favor of Squibb; and the plaintiff, by letter dated April 8, 1987, having requested leave to amend the complaint to add additional allegations to the complaint; and plaintiff's request for leave to amend the complaint having come before the

Court on June 25, 1986, and the Court having granted said request at that time,

NOW, upon reading and filing the Notice of Motion of Upjohn, dated March 2, 1987; the Affidavit of Jay P. Mayesh, Esq., sworn to March 2, 1987, and the exhibits thereto, submitted in support of Upjohn's motion; the Affirmation of William D. Fireman, Esq., dated March 25, 1987, and the Sur-Reply Affirmation of William D. Fireman, Esq., dated April 1, 1987, both submitted in opposition to Upjohn's motion; the Notice of Cross-Motion of Squibb dated March 23, 1987; the Affirmation of William D. Fireman, Esq., dated March 31, 1987, submitted in opposition to Squibb's cross-motion; the Affidavit of Sanford N. Berland, sworn to March 16, 1987, and the exhibit thereto, submitted on behalf of defendant Eli LIlly and Company; the Affirmation of William D. Fireman, Esq., dated July 6, 1987, and the exhibit thereto, submitted in opposition to Upjohn's motion and Squibb's cross-motion; and the motion and the cross-motion having duly come before the Court on July 6, 1987, and plaintiff having appeared by William D. Fireman, Esq., defendant Squibb by Charles M. McCaghey, Esq. and Debra E. Pole, Esq., defendant Upjohn by Jay P. Mayesh, Esq., and defendant Eli Lilly by Russel H. Beatie, Jr., Esq.; and due deliberation having been had thereon, and the Court having rendered a written decision dated July 16, 1987,

NOW, on motion of Stroock & Stroock & Lavan, attorneys for defendant The Upjohn Company, and on cross-motion of Olwine, Connelly, Chase, O'Donnell & Weyher, former attorneys for defendant E.R. Squibb & Sons, Inc., it is

ORDERED that Upjohn's motion for summary judgment and Squibb's cross-motion for partial

summary judgment are denied for the reasons set forth in the Court's decision in *Tigue v. E.R. Squibb & Sons, Inc., et al.*, Index No. 03838/76 (Gammerman, J.), ~~and *Hymowitz v. Eli Lilly & Company, et al.*, Index Nos. 24767/86 and 14848/87*~~ (Gammerman, J.), both dated July 16, 1987.

ENTER,

/S/

J.S.C.

IRA GAMMERMAN

F I L E D
SEP 29 1987
COUNTY CLERK'S OFFICE
NEW YORK

[*Interlineation by the Court.]

APPENDIX H

Order of Supreme Court, New York County
(October 16, 1987)

At an individual Assignment Part 27 of the Supreme Court of the State of New York, held in and for the County of New York, at 60 Centre Street, New York, New York on September 23, 1987.

Present:

HONORABLE IRA GAMMERMAN, Justice.

.....x

JANE DOLAN,

Plaintiff,

-against-

ELI LILLY & COMPANY, E.R. SQUIBB & SONS, INC., THE UPJOHN COMPANY, and WINTHROP-BREON LABORATORIES,

Defendants.

.....x

Assigned to Justice Gammerman
Index No. 23999/86

ORDER

Plaintiff having appeared before this Court on September 18, 1987, and having appeared at that time by Alfred S. Julien, Esq.; and defendant ELI LILLY AND COMPANY having appeared at the aforesaid time by its attorney, Russel H. Beatie, Jr., Esq.; and defendant E.R. SQUIBB & SONS, INC. having appeared at the aforesaid time by its attorney, Barry Epstein, Esq.; and defendant THE UPJOHN COMPANY having appeared at the aforesaid time by its attorney, Jay P. Mayesh, Esq.; and

Plaintiff having moved by oral application for an order granting her partial summary judgment against ELI LILLY AND COMPANY, and severing her claims against it from her claims against THE UPJOHN COMPANY and E.R. SQUIBB & SONS, INC., and having moved for an order severing her claims against ELI LILLY AND COMPANY for trial; and

Defendant ELI LILLY AND COMPANY having moved by oral application on the record staying any trial of the claims against it; and

Defendants ELI LILLY AND COMPANY and E.R. SQUIBB & SONS, INC. having moved by oral application for an order pursuant to Rule 3212 of the Civil Practice Law and Rules granting summary judgment in their favor and dismissing the Complaint against them by the plaintiff on the ground that plaintiff is barred by the applicable Statute of Limitations; and

Defendants ELI LILLY AND COMPANY and E.R. SQUIBB & SONS, INC. having moved by oral application for an order holding L.1986 c.682 §§ 4 and 12 unconstitutional; and

Defendants ELI LILLY AND COMPANY and E.R. SQUIBB & SONS, INC. having moved by oral application for summary judgment dismissing said Complaint against them for plaintiff's failure to allege that ELI LILLY AND COMPANY or E.R. SQUIBB & SONS, INC. was the actual manufacturer of the diethylstilbestrol allegedly ingested; and

Defendant ELI LILLY AND COMPANY having moved for an order precluding the application of collateral estoppel against ELI LILLY AND COMPANY; and

The Court having heard Alfred S. Julien, Esq., of Julien & Schlesinger, P.C., in support of the motion

for partial summary judgment and a severance, and having heard Russel H. Beatie, Jr., Esq., attorney for defendant ELI LILLY AND COMPANY in opposition to said motions and in support of each of the additional motions enumerated above, and having heard Barry Epstein, Esq., attorney for defendant E.R. SQUIBB & SONS, INC. in support of its motion, and the opposition of Alfred S. Julien, Esq.;

NOW, upon motion of Julien & Schlesinger, P.C., it is hereby

ORDERED, that plaintiff's motion for severing the action against ELI LILLY AND COMPANY so that said action can proceed against defendant ELI LILLY AND COMPANY alone is granted; and it is further

ORDERED, that defendant ELI LILLY AND COMPANY, as in *Kaufman v. Eli Lilly and Co.*, 65 N.Y.2d 449, 492 N.Y.S.2d 584, 482 N.E.2d 63 (1985), is precluded from litigating the following:

"1. Was DES reasonably safe in the treatment of accidents of pregnancy when it was allegedly ingested by plaintiff's mother in 1957?

(No)

2. In 1957 when plaintiff's mother allegedly ingested DES, should the defendant, as a reasonably prudent drug manufacturer, have foreseen that DES might cause cancer in the offspring of pregnant woman who took it?

(Yes)

3. Foreseeing that DES might cause cancer in the offspring of pregnant woman who

took it, would a reasonably prudent drug manufacturer test it on pregnant mice before marketing it?

(Yes)

4. If DES had been tested on pregnant mice, would the tests have shown that DES causes cancer in their offspring?

(Yes)

5. Would a reasonably prudent drug manufacturer have marketed DES for use in treating accidents of pregnancy at the time it was allegedly ingested by the plaintiff's mother if it had known that DES causes cancer in the offspring of pregnant mice?

(No);"

and it is further

ORDERED, that the motions of defendants ELI LILY AND COMPANY and E.R. SQUIBB & SONS, INC. for summary judgment in their favor dismissing the Complaint and each cause of action on the ground that the action is barred by the applicable Statute of Limitations are denied; and it is further

ORDERED, that the motions of defendants ELI LILLY AND COMPANY and E.R. SQUIBB & SONS, INC. for summary judgment in their favor dismissing the Complaint and all claims asserted and for an order declaring L.1986 c.682 §§ 4 and 12 unconstitutional are denied; and it is further

ORDERED, that the motions of defendants ELI LILLY AND COMPANY and E.R. SQUIBB & SONS, INC. for summary judgment in their favor in this action dismissing the Complaint against them for plaintiff's failure to allege

that ELI LILLY AND COMPANY or E.R. SQUIBB & SONS, INC. was the actual manufacturer of the diethylstilbestrol are denied; and it is further

ORDERED, that the motion of defendant ELI LILLY AND COMPANY for a stay of trial of this action is denied; and it is further

ORDERED, that defendants ELI LILLY AND COMPANY and E.R. SQUIBB & SONS, INC. shall have until October 14, 1987, and plaintiff until October 21, 1987, to submit such affidavits and other papers as each shall deem appropriate with respect to their relative positions; and it is further

ORDERED, that the trial of the action of *Dolan v. Eli Lilly and Company* is hereby set down for the Court for November 2, 1987.

ENTER,

/S/ IRA GAMMERMAN

J.S.C.

F I L E D
OCT 1987
COUNTY CLERK'S OFFICE
NEW YORK

APPENDIX I

Supplemental Order of Supreme Court
New York County
(August 17, 1988)

SUPREME COURT : NEW YORK COUNTY
IAS : Part 27

.....x

ELIZABETH TIGUE, et al.,

Plaintiffs,

-against-

E.R. SQUIBB & SONS, INC., et al.,

Defendants.

INDEX NO. 03838/76

SUPPLEMENTAL ORDER

.....x

GAMMERMAN, J.:

In its order and memorandum decision entered July 23, 1987, the Court denied the motions and cross-motions for summary judgment of defendants Rexall Drug Company, The Upjohn Company and Abbott Laboratories. Defendant E.R. Squibb & Sons, Inc. ("Squibb") appeared and argued in support of these motions, but was not formally included in this Court's decision. And it appearing that the plaintiff has consented to this application, it is ordered that defendant Squibb shall be deemed to have filed a formal cross-motion for summary judgment on the same grounds as the other defendants, and the order and memorandum decision denying defendants' motions shall be deemed to deny the motion of Squibb *nunc pro tunc*.

DATED: August 17, 1988

IRA GAMMERMAN

J.S.C.

APPENDIX J

Judgment/Remittitur of New York Court of Appeals
(April 4, 1989)

Remittitur

COURT OF APPEALS
STATE OF NEW YORK
The Hon. Sol Wachtler, Chief Judge, Presiding

1 No. 56

Mindy Hymowitz,

Respondent,

Eli Lilly and Company, et al.,

Appellants,

and Merck & Co., Inc., et al.,

Defendants,

Attorney General of the
State of New York,

Intervenor-Respondent.

The appellants in the above entitled appeal appeared by the Law Offices of Russel H. Beatie, Jr., Stroock & Stroock & Lavan, Esqs., Sills Cummis Zuckerman Radin Tischman Epstein & Gross, P.A., Patterson Belknap Webb & Tyler, Esqs., Dickson, Carlson & Campillo, Esqs.; *the respondent(s) appeared by* Rheingold & McGowan, P.C.; the Office of the Attorney General appeared by Andrea Green, Esq.; and the amicus curiae appeared by New York Lawyers for the Public Interest, Inc.

The Court, after due deliberation, orders and adjudges that the order is affirmed, with costs, and certified question answered in the affirmative. Opinion by Chief Judge Wachtler. Judges Alexander, Titone and Hancock concur. Judge Mollen concurs in a separate opinion. Judges Simons, Kaye and Bellacosa took no part.

The Court further orders that the papers required to be filed and this record of the proceedings in this Court be remitted to the Supreme Court, New York County,

I certify that the preceding contains a correct record of the proceedings in this appeal in the Court of Appeals and that the papers required to be filed are attached.

/S/ DONALD M. SHERAW

Donald M. Sheraw, Clerk of the Court

Court of Appeals, Clerk's Office, Albany,. . .April 4, 1989. . .

APPENDIX K

Judgment/Remittitur of New York Court of Appeals
(April 4, 1989)

Remittitur

COURT OF APPEALS
STATE OF NEW YORK
The Hon. Sol Wachtler, Chief Judge, Presiding

1 No. 57

Elizabeth Tigue, et al.,

Respondents,

v.

E.R. Squibb & Sons, Inc., et al.,

Appellants,

et al.,

Defendants.

The appellants in the above entitled appeal appeared by the Sills Cummis Zuckerman Radin Tischman Epstein & Gross, P.A., Hughes Hubbard & Reed, Esqs., Stroock & Stroock & Lavan, Esqs., McCarter & English, Esqs., Patterson Belknap Webb & Tyler, Esqs., Dickson, Carlson & Campillo, Esqs.; Phillips Lytle Hitchcock Blaine & Huber, Esqs., Winthrop Stimson Putnam & Roberts, Cole & Deitz, Esqs. and Olwine Connelly Chase O'Donnell & Weyher, Esqs.; *the respondent(s) appeared by* Aaron J. Broder, P.C. and Rheingold & McGowan, P.C.

The Court, after due deliberation, orders and adjudges that the order is affirmed, with costs, and certified question answered in the affirmative. Opinion by Chief Judge Wachtler. Judges Alexander, Titone and Hancock concur. Judge Mollen dissents in part and votes to modify in an opinion. Judges Simons, Kaye and Bellacosa took no part.

The Court further orders that the papers required to be filed and this record of the proceedings in this Court be remitted to the Supreme Court, New York County, *there to be proceeded upon according to law.*

I certify that the preceding contains a correct record of the proceedings in this appeal in the Court of Appeals and that the papers required to be filed are attached.

/S/ DONALD M. SHERAW

.....

Donald M. Sheraw, Clerk of the Court

Court of Appeals, Clerk's Office, Albany,. . . April 4, 1989 . . .

APPENDIX L

Judgment/Remittitur of New York Court of Appeals
(April 4, 1989)

Remittitur

COURT OF APPEALS
STATE OF NEW YORK
The Hon. Sol Wachtler, Chief Judge, Presiding

1 No. 57

Jane Dolan, et al.,

Respondents,

v.

Eli Lilly & Company, et al.,

Appellants,

(and other actions.) #151 actions.

The appellants in the above entitled appeal appeared by the Law Offices of Russel H. Beatie, Stroock & Stroock & Lavan, Esqs., Sills Cummis Zuckerman Radin Tischman Epstein & Gross, P.A., Cole & Deitz, Esqs., Dickson, Carlson & Campillo, Esqs.;

the respondent(s) appeared by Julien & Schlesinger, P.C. and Sybil Shainwald, Esq.

The Court, after due deliberation, orders and adjudges that the order is affirmed, with costs, and certified question answered in the affirmative. Opinion by Chief Judge Wachtler. Judges Alexander, Titone and Hancock concur. Judge Mollen dissents in part and votes to modify in an opinion. Judges Simons, Kaye and Bellacosa took no part.

The Court further orders that the papers required to be filed and this record of the proceedings in this Court be remitted to the Supreme Court, New York County, *there to be proceeded upon according to law.*

I certify that the preceding contains a correct record of the proceedings in this appeal in the Court of Appeals and that the papers required to be filed are attached.

/S/ DONALD M. SHERAW

.....

Donald M. Sheraw, Clerk of the Court

Court of Appeals, Clerk's Office, Albany, . . April 4, 1989. . .

APPENDIX M

Excerpt from "Brief of Defendant-Appellant E.R. Squibb & Sons, Inc.," filed November 8, 1988, in New York Court of Appeals in *Tigue v. E.R. Squibb & Sons, Inc.* (fn. 4, pp. 12-13):

4. The legislature is best able to resolve the issues of public policy involved in this case. In the joint brief submitted by defendants Merck, Abbott, and Lilly, it is forcefully argued that the adoption of any form of non-identification liability will severely restrict the availability of pharmaceutical products in the future. Squibb concurs with the public policy discussion contained in that brief. Squibb also concurs with, and hereby adopts, that section of the joint brief which contends that any form of non-identification liability is unconstitutional. Defendants' due process rights are violated because they will be held liable for injuries sustained by plaintiffs who were not exposed to their product. Further, such liability also imposes an irrebuttable presumption of causation upon defendants.

APPENDIX N

Excerpt from "Brief on Behalf of Defendants-Appellants Abbott Laboratories, Eli Lilly and Company and Merck & Co., Inc." filed November 8, 1988, in the New York Court of Appeals in *Tigue v. E.R. Squibb & Sons, Inc.* (pp. 31-34):

D. Any Theory of Non-Identification Liability Would Violate Defendants' Due Process Rights.

The due process clause of the Fourteenth Amendment to the United States Constitution and Section 6 of Article I of the New York State Constitution prohibit any deprivation of property without due process of law. The due process clause affords protection against "arbitrary action government," *Wolff v. McDonell*, 418 U.S. 539 (1974), and its protection extends to arbitrary actions of judicial as well as legislative bodies. For an action of a court or a legislature to pass muster under the due process clause, there must be a rational relation between a legitimate state interest, and the judicial or legislative means chosen to further that interest.

By eliminating proof of identification from plaintiff's case, this Court would effectively create a mandatory presumption of causation. That is, a manufacturer would be presumed to be the cause of plaintiff's injury even though it has nothing to do with plaintiff. Indeed, as a practical matter, this presumption would be irrebuttable since defendants in many cases will be unable to prove they did not make the medicine that plaintiffs claim caused injury. Such a presumption is a violation of defendants' due process rights. *Vlandis v. Kline*, 412 U.S. 441, 446 (1976);[21] *Hurley v. Van Lare*, 380 F.Supp.

[21] A mandatory presumption tells the trier of fact "that he or they must find the elemental fact upon proof of the basic fact, at least until the defendant has come forward with some evidence to rebut the presumed connection between the two facts." *County Court of Ulster County v. Allen*, 442 U.S. 140, 157 (1978) (emphasis supplied).

167, 175 (S. and E.D.N.Y. 1974) (three judge district court), *vacated as moot*, 421 U.S. 338 (1975).

In order for such a preseumption to withstand due process scrutiny, it must be neither unreasonable nor irrational. *See, e.g., U.S. Dept. of Agriculture v. Murry*, 413 U.S. 508, 514 (1973). Such a presumption valid under the due process clause. *Vlandis*, 412 U.S. at 441.

As a number of courts have recognized in the DES context, any theory which shifts the burden to defendants to disprove causation creates an irrational and unreasonable presumption of liability because there is no certainty that any one or more of the defendants joined in an action produced the drug in question. *Ryan v. Eli Lilly & Co.*, 514 F.Supp. at 1018; *Mizell v. Eli Lilly & Co.*, 526 F.Supp. 589, 596 (D.S.C. 1981); *Tidler v. Eli Lilly & Co.*, 95 F.R.D. 332, 333 (D.D.C. 1982).

There must be a "rational connection between the fact proved and the fact presumed." *Leary v. United States*, 395 U.S. 6, 32-37 (1969) (presumption irrational unless it can be said with substantial assurance that the presumed fact is *more likely than not to flow* from the proved fact on which it is made to depend. [sic]" (emphasis added)); *Tot v. United States*, 319 U.S. 463 (1943). These rules governing presumptions apply not only to the statutory presumptions at issue in *Tot* and *Leary*, but to judicially created presumptions as well. *Wray v. Folsom*, 166 F.Supp. 390, 395 (W.D. Ark. 1958).

Here, the proved fact is that a defendant made stilbestrol. In most DES cases, there is no proof that any defendant made the stilbestrol ingested by a particular plaintiff. Indeed, in some cases, there is affirmative proof that the defendants did not. With literally hundreds of possible manufacturers, most of them not before the Court, the probability that any one

defendant supplied the product which caused the injury is at best pure conjecture. Any theory which permits plaintiffs to prevail, then, must depend on a conclusive presumption that because a defendant sold a product similar to the one that caused the injury, the defendant's conduct caused the injury. Such a theory rests on an illogical presumption, and fails to satisfy the requirements of due process.

E. The First Department's Rule of Conscious Parallelism Is A Particularly Egregious Violation of Defendants' Due Process Rights.

The First Department's conscious parallelism theory is particularly egregious in its disregard for defendants' constitutional rights. By equating legitimate parallel business behavior with "concerted action," conscious parallelism creates an arbitrary and irrebuttable presumption which violates the due process clauses of the fourteenth Amendment and article I, § 6 of the Constitution of the State of New York.

The constitutional prohibition against such types of presumptions was best stated by the Supreme Court of the United States in *Western & Atl. R.R. v. Henderson*, 279 U.S. 639 (1928), when it struck down a statute establishing a conclusive presumption against a railroad company for damages to any person or property injured at a crossing—a presumption rebuttable only if the company made it clear that it exercised all due care. The Court said, "[a] statute creating a presumption that is arbitrary or that operates to deny a fair opportunity to repel it violates the due process clause of the Fourteenth Amendment." 279 U.S. at 642. The Court has been consistent in striking down such presumptions. *See, e.g., Vlandis*, (invalidating Connecticut statute establishing a presumption of nonresidency against

certain students and requiring them to pay higher tuition rates); *Cleveland Bd. of Education v. LaFleur*, 414 U.S. 632 (1973) (striking down mandatory maternity leave statute on the ground that it established a conclusive presumption that every teacher who is four or five months pregnant is physically incapable of continuing her duties).

Application of conscious parallelism here would also have the *retroactive* effect of holding defendants liable for behavior which was not actionable at the time the behavior was undertaken some thirty or forty years ago. Regardless of the fact that the First Department has now declared consciously parallel behavior actionable and punishable with joint and several liability, defendants could not be fairly said to have had warning that any nontortious parallel conduct in which they independently engaged in 1941 or 1947 would someday be the basis for the imposition of joint and several liability. This retroactive application of the rule violates due process. *Chase Sec. Corp. v. Donaldson*, 325 U.S. 304 (1945); *Valladares v. Valladares*, 80 A.D.2d 224, 438 N.Y.S.2d 810 (2d Dept.), *modified sub nom., Tucker v. Tucker*, 55 N.Y.2d 378, 434 N.E.2d 1050, 449 N.Y.S.2d 863 (1981) (retroactive application of new legislation may offend due process clause); *cf. Marks v. United States*, 430 U.S. 188, 191-192 (1977); *see also Casillas v. Scully*, 769 F.2d 60, 65 (2d Cir. 1985) (finding that "unforeseeable" judicial enlargement of a criminal statute is violative of the due process clause).[22] It is the very reason

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[22]The offense to state protected due process is equally clear. The reach of the protections afforded by the Bill of Rights in the New York State Constitution is equal to and in some cases even exceeds that of the comparable clauses of the United States Constitution. *People v. Adams*, 53 N.Y.2d 241, 423 N.E.2d 379, 383, 440 N.Y.S.2d 902, 906 (1981).

why courts presume that unless clearly stated legislation creating new rights is prospective only, *Jacobus v. Colgate*, 217 N.Y. 235 (1916); *In re Ayman*, 9 N.Y.2d 119, 125, 172 N.E.2d 571, 573, 211 N.Y.S.2d 198, 200-201 (1961); and where retroactivity expressly intended by the legislature would offend due process, the statute is not upheld. *Chrysler Properties, Inc. v. Morris*, 23 N.Y.2d 515, 297 N.Y.S.2d 115 (1966); *Phillips v. Agway, Inc.*, 88 Misc. 2d 1087, 389 N.Y.S.2d 977 (Sup. Ct. 1976).[23]

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[23] *Bichler* may also violate the first amendment if the "evidence" relied upon to prove "consciously parallel behavior" is the petitioning of the government for the approval of the drug in 1941 or 1947. In *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), the Court held that railroads that petitioned the legislature in order to achieve laws harmful to competitors could not be held to have violated the Sherman Act because such activities were protected by the first amendment. Although originally developed in antitrust cases, the Noerr doctrine has been extended to petitioning other branches of government, *e.g.*, *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965), and to other areas of the law including allegedly tortious behavior, *State of Missouri v. Nat'l Org. for Women, Inc.*, 620 F.2d 1301, 1317-1319 (8th Cir. 1980), *cert. denied*, 449 U.S. 842 (1980); *Feminist Women's Health Center v. Mohammad*, 586 F.2d 530, 542 (5th cir. 1978), *cert. denied*, 444 U.S. 924 (1979); *Senart v. Mobay Chem. Corp.*, 597 F.Supp. 502, 506 (D. Minn. 1984).

APPENDIX O

Excerpt from "Brief of Defendant-Appellant E.R. Squibb & Sons, Inc. Relying Upon Its Brief In *Hymowitz v. Eli Lilly* and *Tigue v. E.R. Squibb & Sons Inc.*," filed November 8, 1988 in *Dolan v. Eli Lilly & Co.* (p.1):

This appeal presents two issues which have been fully briefed by defendant-appellant E. R. Squibb & Sons, Inc. (Squibb) in two other appeals which are currently before this court. The first issue presented in this appeal is the constitutionality of the revival statute (L.1986, ch. 682 §4), and Squibb hereby adopts its principal brief and reply brief filed in *Hymowitz v. Eli Lilly & Co.*, App. Div. Case No. 31981. The second issue presented by this appeal is the viability of any "non-identification" form of liability, and Squibb hereby adopts its principal brief (and reply brief, if one is filed) in *Tigue v. E. R. Squibb & Sons, Inc.*, App. Div. Case No. 31980.

APPENDIX P

Excerpt from "Brief of Appellant E.R. Squibb & Sons, Inc." filed November 16, 1987 in New York Supreme Court, Appellate Division, First Department, in *Dolan v. Eli Lilly & Co.* (pp. 63-69), and *Tigue v. E.R. Squibb & Sons Inc.*, (pp. 63-68):

X.

Any Form of Liability Without Proof of Causation Would Be Unconstitutional, Because There Would Be a Presumption of Causation Without Any Rational Basis.

Due process is denied where a defendant is subject to liability for an injury having no causal connection to that particular defendant's conduct. The essence of any modified theory of liability is that it dispenses with the requirement of a plaintiff proving cause in fact, a connection between a particular defendant's conduct and the plaintiff's claimed injury. In such a context, a plaintiff is allowed to sue one or all of the members of an industry, all of whom may be held liable to the plaintiff, even though only one out of several hundred members of the industry may have actually harmed the plaintiff. It is submitted that the abandonment of causation as an element of a cause of action, through the fiction of shifting the burden of proof, constitutes a violation of each defendant's separate right to due process of law.

The "touchstone" of due process is protection of a party against "arbitrary action of government." *Wolff v. McDonald*, 418 U.S. 539, 558 (1974). A rule of law permitting one individual to sue selectively an entire industry with hundreds of members, for the conduct of only one member, or the conduct of no member, constitutes such arbitrary action.

In *Stanley v. Illinois*, 405 U.S. 645 (1972), the Supreme Court invalidated a state law that established a presumption that an unwed father is an unsuitable parent. It was held that such a presumption violates due process, and that every unwed father is entitled a particularized determination of parental fitness on the basis of individualized proof. Similarly, in *Boddie v. Connecticut*, 401 U.S. 371 (1971), it was held that the due process clause requires that each defendant have a separate and meaningful opportunity to be heard. A rule may "offend due process because it operates to foreclose a particular party's opportunity to be heard." 401 U.S. at 380. A state "owes to each individual that process which, in light of the values of a free society, can be characterized as due." 401 U.S. at 380. Any modified theory of liability violates the principles of *Stanley* and *Boddie* because it lumps the defendants together as an entity, failing to recognize that each defendant has separate and independent constitutional protections. Since the constitution requires an individualized determination of each defendant's liability, the fundamental burden of proving causation cannot be satisfied by considering the defendant as a group. There must be evidence of the conduct of each defendant individually and as to each element of liability.

In *Vachon v. New Hampshire*, 414 U.S. 478, *reh. den.*, 415 U.S. 952 (1974), the United States Supreme Court struck down a conviction based on a record lacking any relevant evidence as to a crucial element of a particular offense. It was held that such a conviction violated due process. The state was not allowed to simply dispense with an element of an offense. It is constitutionally required that the prosecution must convince the trier of fact of all essential elements of guilt. *In Re Winship*, 397 U.S. 358, 362 (1970).

On occasion, states have attempted to dispense with the requirement of proving an element of a criminal offense by shifting the burden of proof on the issue to the defendant. In *Mullaney v. Wilbur*, 421 U.S. 684 (1975), theSupreme Court rejected such an attempt. The doctrine of the Winship case was applied so as to preclude shifting the burden of proof on the defendant's state of mind. Similarly, the Mullaney court noted that the Winship doctrine could not be avoided simply by redefining the elements which constitute various crimes. 421 U.S. at 698.

The above cases demonstrate that, although states have considerable latitude in establishing procedures, they may not arbitrarily tamper with the elements of an offense or a cause of action, which are established by the traditions and conscience of our people. States may not achieve this end by purporting to shift the burden of proof to a defendant.

The requirement of establishing a causal connection between a defendant's conduct and his civil or criminal liability is, it is submitted, rooted in the most fundamental beliefs of our people. It is a violation of due process to convict and punish a man without evidence of his guilt. *Thompson v. City of Louisville*, 362 U.S. 199, 206 (1960). Similarly, it is a violation of due process to impose civil liability on the defendant who, demonstrably, never harmed the plaintiff.

The principles of the above cases are applicable to both civil and criminal proceedings. The United Supreme Court has consistently rejected efforts to eliminate required elements of a cause of action or an offense, or arbitrarily shift the burden of proof in violation of due process.

Furthermore, due process is unavailable where a State creates a presumption of causation having no rational basis in fact or in legal precedent. To shift the burden of proof on causation to each of the defendants is, in effect, to create a mandatory presumption of causation. A mandatory presumption is a "troublesome evidentiary device." *County Court of Ulster County v. Allen*, 442 U.S. 140, 99 S.Ct. 2213, 2224 (1979). Such a presumption is one that tells the judge or jury that "he or they must find the elemental fact upon proof of the basic fact, at least unless the defendant has come forward with some evidence to rebut the presumed connection between the two facts." 99 S.Ct. at 2224-2225.

A theory of group liability without identification undoubtedly can be classified as a "mandatory presumption." Plaintiff need merely demonstrate prenatal exposure to DES and that a particular defendant was a manufacturer or supplier of the type of product involved. It is then presumed that the plaintiff was exposed to the particular defendant's product, unless the defendant can demonstrate that its product could not have reached the plaintiff. Such an unusual case might occur where, for example, a particular defendant entered the national market after the time that the plaintiff was exposed to DES. However, in the absence of such evidence, the presumption of causation operates against all of the defendants in the market place.

It should be noted that judicially created presumptions are subject to the same constitutional scrutiny as those established by legislation. *Wray v. Folsom*, 166 F.Supp. 390, 395 (W.D. Ark. 1958). In order for a presumption to pass constitutional muster, there must be "some rational connection between the fact proved and the ultimate fact presumed, and that the inference of one fact from proof of another shall not be so unreasonable

as to be purely arbitrary mandate." *Mobile, Jackson & Kansas City Railroad Company v. Turnipseed,* 219 U.S. 35, 43 (1910). This rule is applicable "in either criminal or civil cases" and a presumption must not "shut out from the party affected a reasonable opportunity to submit to the jury in his defense all of the facts bearing upon the issue." 219 U.S. at 43.

In *Manley v. Georgia*, 279 U.S. 1 (1929), for example, the United States Supreme Court reviewed the constitutionality of a Georgia banking law which established a presumption of fraud upon proof of a bank's insolvency. From the mere failure of the bank financially, criminal guilt and apparently civil liability were created, subject only to the right of the defendant to rebut the presumption. This liability extended to the president of the bank and all of its directors.

Unsurprisingly, the conviction of Mr. Manley was overturned by the Supreme Court, which found that the statutory presumption was unreasonable and arbitrary. It was noted that insolvency could be established without regard to the particular facts causing it, and without regard to specific facts of any particular transaction. Furthermore, the court noted that the presumption was "sweeping," extending to all directors without proof of any individual responsibility. 279 U.S. at 6. Under the statute, a defendant "is to be convicted unless he negatives every fact, whether act or omission in the management of the bank, from which fraudulent insolvency might result, or shows that he is in no way responsible for the condition of the bank." 279 U.S. at 7. Such a burden of proving a negative was held so severe as to be unconstitutional.

More recent cases have condemned the use of presumptions as substitutes for individual fact finding.

See, for example, *Cleveland Board of Education v. La Fleur*, 414 U.S. 632, 649 (1974). Presumptions which are neither necessarily nor universally true are disfavored under the Constitution "because they preclude individualized determination of the facts upon which substantial rights or obligations may depend." *Coleman v. Darden*, 595 F.2d 533, 536 (10th Cir. Colo. 1979), *cert. den.*, 444 U.S. 927 (1979).

Also, due process is violated when a defendant is subject to civil liability merely because of its status as a manufacturer, and not because of any particular conduct. The foundation of both criminal and civil liability is conduct on the part of the defendant. In either case, there must be an act or omission in violation of society's rules of conduct and, in the civil case, the conduct must have injured the plaintiff. A defendant cannot be held liable simply for his status, however disagreeable that may be.

The distinction between a defendant's "status" and his "conduct" was drawn in the leading case of *Robinson v. State of California*, 370 U.S. 660, *reh. den.*, 371 U.S. 905 (1962). In *Robinson*, a conviction was reversed which may have been based on the defendant's "status" as a narcotics addict, as distinguished from any use, possession, or sale of a narcotic substance.

It might be possible to infer that any narcotics addict must have, at some time, illegally possessed or used a prescribed substance. However, the Supreme Court held that the constitution requires proof of the actual illegal conduct, as distinguished form [sic] the status ultimately resulting from that conduct.

A modified theory of liability relieving plaintiff of her burden of product identification permits civil liability on the part of a defendant solely because of its status

as a manufacturer or supplier of DES. This is true, even though each defendant separately appeared in the market place, complied with the requirements of federal law regulating drugs, and separately distributed its product. It is submitted that no state may constitutionally create liability in favor of a single person against all parties enjoying the "status" of manufacturer or supplier of a particular product.